SCIENTIFIC PANEL ON GMO

Minutes of the 79th Plenary meeting of the Scientific Panel on GMO

Held on 23–24 January 2013, Parma

(Agreed on 6 March 2013)

Participants

- **Panel members**:

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

- **Hearing experts**:

None.

- **EFSA:**

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

- **Other EFSA Units/Directorates:** Jordi Serratosa (SCOM Unit / SCISTRAT Directorate[1]), Andras Szoradi (P&M SCISTRAT Directorate[2]), Per Bergman (REPRO Directorate[3]).
- **European Commission observers:** Martine Delanoix, Sabine Pelsser and Meta Varady (DG SANCO).
- **Observers (in application of the guidelines for observers[4])**: none.
- **Others:** none.

1. Welcome and apologies for absence

The Chair welcomed the participants.

Apologies were received from Jürgen Gropp and Kaare Nielsen.

[1] Scientific Committee (SCOM) Unit of the Science Strategy and Coordination (SCISTRAT) Directorate
[2] Planning and Monitoring (P&M) team of the Science Strategy and Coordination (SCISTRAT) Directorate
[3] Scientific Evaluation of Regulated Products Directorate
[4] http://www.efsa.europa.eu/en/stakeholders/observers.htm

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) 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 for the present meeting. No conflicts of interests related to the issues discussed in this meeting have been 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 78th Plenary meeting held on 5-6 December 2012, Parma

The minutes of the 78th GMO Plenary meeting (5-6 December 2012) were adopted and will be published at: http://www.efsa.europa.eu/en/events/event/130123a.htm

5. Report on written procedures since the 78th Plenary meeting

There have been no written adoptions since the 78th Plenary meeting.

6. Scientific outputs submitted for discussion and possible adoption

6.1 Scientific Opinion on application (EFSA-GMO-NL-2010-87) for the placing on the market of genetically modified herbicide tolerant oilseed rape GT73 for food containing or consisting of, and food produced from or containing ingredients produced from, oilseed rape GT73 (with the exception of processed oil and food additives) under Regulation (EC) No 1829/2003 from Monsanto (EFSA-Q-2010-01088)

This scientific opinion is a risk assessment for the placing on the market of the genetically modified (GM) herbicide-tolerant oilseed rape (OSR) GT73 for food containing or consisting of, and food produced from or containing ingredients produced from, OSR-GT73. OSR-GT73 contains a single insert consisting of the goxv247 and CP4 epsps expression cassettes. Both proteins confer tolerance against glyphosate-based-herbicides. Bioinformatic analyses of inserted DNA and flanking regions did not raise safety concerns. Levels of CP4 EPSPS and GOXv247 proteins in OSR-GT73 were analysed and the stability of the genetic modification was demonstrated. No biologically relevant differences were identified in the compositional/agronomic/phenotypic characteristics of OSR-GT73 compared with its conventional counterpart, except for the newly expressed proteins. No indication of potential concerns over the safety of the newly expressed CP4-EPSPS and GOXv247 proteins or the occurrence of unintended effects were identified in either OSR-GT73 pollen/pollen-containing dietary supplements or the adventitious presence of trace levels of seeds in human foods. An equivalent assessment with isolated seed protein could not be made because of the lack of availability of relevant consumption and safety data. There are no indications of increased establishment and spread of feral OSR-GT73 plants, or of hybridising wild relatives, unless exposed to glyphosate-based-herbicides. Potential interactions of feral plants with the biotic/abiotic environment do not raise concerns. Environmental risks of horizontal gene

transfer into bacteria were not identified. The monitoring plan and reporting intervals are in line with the intended uses. The environmental risk assessment of OSR-GT73 did not identify any safety concerns, in the context of its intended uses. While the Panel is not in a position to conclude on the safety of OSR pollen as such, it concludes that the genetic modification in OSR-GT73 does not constitute an additional health risk if OSR-GT73 pollen were to replace non-GM OSR pollen.

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 Application for authorisation of genetically modified maize 59122 and derived food and feed including cultivation submitted under Regulation (EC) No 1829/2003 by Pioneer (EFSA-GMO-NL-2005-23) (EFSA-Q-2005-250)

The EFSA GMO Panel discussed the draft scientific opinion, with a particular focus on the environmental 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 MON89034x1507xNK603xDAS-40278-9 grain for all uses, excluding cultivation, according to Regulation (EC) No 1829/2003, submitted by Dow AgroSciences (EFSA-GMO-NL-2013-112) (EFSA-Q-2013-00079)

7.2 Annual post-market environmental monitoring reports of GM plants

None.

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

- **Work distribution between Working Groups (WGs)**

The GMO Panel agreed on the work distribution between Molecular Characterisation and Food/Feed WGs with regard to protein equivalence testing and bioinformatic analyses. The GMO Panel also discussed the collaboration of the Environment WG with the Food/Feed WG on the comparative assessment of the agronomic and phenotypic characteristics of a GM crop.

- **Risk assessment of stacked events**

The GMO Panel discussed various aspects of the risk assessment of GM stacked events, such as: criteria for the selection of comparator, field trial design, assessment of sub-combinations, potential interactions of events. Further discussion is needed.

- **Risk to non-target Lepidoptera from Bt maize pollen**

The Chair of the GMO Panel reported that the Environment Working Group had discussed a paper critical of the model forming the basis of two Opinions relating to EFSA-Q-2012-00712 and EFSA-Q-2012-00820, adopted in late 2012. The initial assessment by the Environment Working Group was that there was no scientific information in the paper that would change or invalidate the conclusions of these two previous risk assessments; further discussion is needed.

8.3 EFSA

- **Overview of the current activities of EFSA in US**

An officer of EFSA's SCISTRAT Directorate presented to the GMO Panel the activities in which EFSA collaborates with the US Food and Drug Administration (FDA).

- **Discussion on EFSA and REPRO Directorate**

The Director of the REPRO Directorate and the GMO Panel discussed EFSA's initiative to enhance transparency of the risk assessment.

- **Attendance of observers at EFSA Scientific Committee/Panel meetings**

An officer of EFSA's SCISTRAT Directorate presented to the GMO Panel the guidelines for observers attending Scientific Committee/ Scientific Panel Plenary meetings.

8.4 European Commission

- **Update on draft Food/Feed Regulation status**
- **Possible generic mandates**

A member of the European Commission informed the GMO Panel about two safeguard clauses submitted by Austria.

9. Other scientific topics for information and/or discussion

- **Guidance on the environmental risk assessment of GM animals**

The GMO Panel discussed the current status of this guidance document. Its adoption is foreseen for the April Plenary meeting of the GMO Panel.

10. Any other business

- **GMO Panel outputs of 2012 and workplan for 2013**

The Head of the GMO Unit presented to the Panel an overview of the scientific opinions, guidance documents and Panel statements that were adopted in 2012, and an estimation of the number of Panel outputs foreseen for 2013.

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.