European Food Safety Authority

GMO UNIT

SCIENTIFIC PANEL ON GMO

Minutes of the 78th Plenary meeting of the Scientific Panel on GMO

Held on 5–6 December 2012, Parma

(Agreed on 23 January 2013)

Participants

- **Panel members**:

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

- **Hearing experts**:

None.

- **EFSA:**

GMO Unit: 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, Stefano Rodighiero and Elisabeth Waigmann.

- **Other EFSA Units/Directorates:** Daniela Maurici (SCOM Unit / SCISTRAT Directorate[2]), Elisa Aiassa (SAS Unit / RASA Directorate[3]), Roy Kirby (EXO Unit / Executive Directorate[4]), Per Bergman (REPRO Directorate[5]).
- **European Commission observers:** Martine Delanoix (DG SANCO).
- **Observers (in application of the guidelines for observers[6])**: none.
- **Others:** none.

1. Welcome and apologies for absence

The Chair welcomed the participants and informed the GMO Panel about the resignation from her role as a Panel member of Pagona Lagiou.

[1] Present via teleconference on 5 December for item 6.6 of the agenda.
[2] Scientific Committee (SCOM) Unit of the Science Strategy and Coordination (SCISTRAT) Directorate
[3] Scientific Assessment Support (SAS) Unit of the Risk Assessment and Scientific Assistance (RASA) Directorate
[4] Executive Office (EXO) Unit of the Executive Directorate
[5] Scientific Evaluation of Regulated Products Directorate
[6] 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)[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 for the present meeting. For further details on the outcome of the screening of the ADoI and SDoI, please refer to Annex I.

4. Agreement of the minutes of the 77th Plenary meeting held on 17-18 October 2012, Parma

The minutes of the 77th GMO Plenary meeting (17-18 October 2012) were adopted and will be published at: http://www.efsa.europa.eu/en/events/event/121205b.htm

5. Report on written procedures since the 77th Plenary meeting

There have been no written adoptions since the 77th Plenary meeting.

6. Scientific outputs submitted for discussion and possible adoption

6.1 Scientific Opinion updating the risk assessment conclusions and risk management recommendations on the genetically modified insect resistant maize MON 810 (EFSA-Q-2012-00711)

Following a request from the European Commission, the Panel on Genetically Modified Organisms of the European Food Safety Authority (EFSA GMO Panel) compiled its previous risk assessment conclusions and risk management recommendations on the genetically modified insect resistant maize MON 810, and considered their validity in the light of new relevant scientific publications published from 2009 onwards. Following a search of the scientific literature published between 2009 and October 2012, the EFSA GMO Panel identified 165 peer-reviewed publications containing evidence specific to the risk assessment and/or management of maize MON 810, of which 68 publications were discussed and/or cited in previous EFSA GMO Panel scientific outputs. From the remaining 97 publications, eight were relevant for the molecular characterisation, 27 for food and feed safety assessment, 55 for the environmental risk assessment and/or risk management, two for the molecular characterisation and the environmental risk assessment and/or risk management and five for the food and feed safety assessment and the environmental risk assessment and/or risk management of maize MON 810. None of these publications reported new information that would invalidate the previous conclusions on the safety of maize MON 810 made by the EFSA GMO Panel. Therefore, the EFSA GMO Panel considers that its previous risk assessment conclusions on maize MON 810, as well as its previous recommendations on risk mitigation measures and monitoring, remain valid and applicable.

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 updating the risk assessment conclusions and risk management recommendations on the genetically modified insect resistant maize Bt11 (EFSA-Q-2012-00713)

Following a request from the European Commission, the EFSA GMO Panel compiled its previous risk assessment conclusions and risk management recommendations on the genetically modified insect resistant maize Bt11, and considered their validity in the light of new relevant scientific publications published from 2005 onwards. Following a search of the scientific literature published between 2005 and October 2012, the EFSA GMO Panel identified 287 peer-reviewed publications containing evidence specific to the risk assessment and/or management of maize Bt11, of which 270 publications were previously discussed and cited in relevant GM maize-related applications and/or the numerous EFSA GMO Panel scientific outputs. From the remaining 17 publications, three were relevant for the food and feed safety assessment, and 14 for the environmental risk assessment and/or risk management of maize Bt11. None of these publications reported new information that would invalidate the previous conclusions on the safety of maize Bt11 made by the EFSA GMO Panel. Therefore, the EFSA GMO Panel considers that its previous risk assessment conclusions on maize Bt11, as well as its previous recommendations on risk mitigation measures and monitoring, remain valid and applicable.

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 Scientific Opinion supplementing the conclusions of the environmental risk assessment and risk management recommendations for the cultivation of the genetically modified insect resistant maize Bt11 and MON 810 (EFSA-Q-2012-00820)

The EFSA GMO Panel was asked by the European Commission to apply its mathematical model to simulate and assess potential adverse effects resulting from the exposure of non-target Lepidoptera to maize Bt11 or MON 810 pollen under hypothetical agricultural conditions, and to provide information on the factors affecting the insect resistance management plan, additional to that in its 2011 Statement supplementing the evaluation of the environmental risk assessment and risk management recommendations on insect resistant genetically modified maize Bt11 for cultivation. Here, risk managers are provided with additional evidence and further clarifications to those previous conclusions and risk management recommendations. This Scientific Opinion provides background scientific information to inform the decision-making process; the EFSA GMO Panel reiterates that risk managers should choose risk mitigation and management measures that are proportionate to the level of identified risk according to the protection goals pertaining to their regions.

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

6.4 Scientific Opinion on the annual Post-Market Environmental Monitoring (PMEM) report from BASF Plant Science Company GmbH on the cultivation of genetically modified potato EH92-527-1 in 2011 (EFSA-Q-2012-00643)

Following a request from the European Commission, the EFSA GMO Panel assessed the monitoring report for the 2011 growing season, provided by BASF, on the genetically modified (GM) potato EH92-527-1 (variety Amflora). On 26 January 2012, the EFSA GMO

Panel had adopted a scientific opinion on the 2010 monitoring report on potato EH92-527-1. The EFSA GMO Panel followed the same approach as for the assessment of the 2010 monitoring report and assessed, in close collaboration with the EFSA Unit for Scientific Assessment Support, the methodology used by the applicant in 2011 for the case-specific studies, the general surveillance of potato EH92-527-1 and the field study to monitor potential adverse effects on potato-feeding organisms as required in the related Commission Decision. The EFSA GMO Panel notes similar shortcomings in the methodology for general surveillance and for the specific field study on potato-feeding organisms as were found in the 2010 monitoring report. Hence, the EFSA GMO Panel reiterates the same recommendations for improvement of the methodology for the post-market environmental monitoring of potato EH92-527-1 as it did in its scientific opinion on the 2010 monitoring report. The EFSA GMO Panel also assessed the methodology of a new study monitoring GM volunteers within and around fields cropped with potato EH92-527-1 in 2010. The EFSA GMO Panel identified flaws in that study and therefore makes recommendations to the applicant to improve the study design. However, from the overall dataset submitted by the applicant, the EFSA GMO Panel did not identify adverse effects on the environment or human and animal health due to potato EH92-527-1 cultivation. The outcomes of the 2011 monitoring report do not invalidate the conclusions of the EFSA GMO Panel's previous opinions on potato EH92-527-1.

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

6.5 Scientific Opinion on a request from the European Commission for the assessment of the scientific elements put forward by Hungary to support the prohibition for the placing on the market of GM potato EH92-527-1 for cultivation purposes in Hungary (EFSA-Q-2012-00615)

Hungary notified to the European Commission its scientific arguments justifying the implementation of a national safeguard measure prohibiting the placing on the market of GM potato EH92-527-1 for cultivation purposes in Hungary, after which the European Commission asked the European Food Safety Authority (EFSA) to assess the scientific information supporting the prohibition. Having considered the information package provided by Hungary and all relevant scientific publications, the EFSA GMO Panel concluded that (i) no new data specific to the safety of the *npt*II gene have been provided; (ii) the therapeutic relevance of kanamycin and neomycin was already addressed in the previous EFSA opinion on antibiotic resistance marker genes and kanamycin resistance in *Mycobacterium tuberculosis* results largely from chromosomal mutations and not from the transfer of aminoglycoside resistance genes such as *npt*II; (iii) the knowledge gaps and uncertainties highlighted in the Hungarian document have already been considered in the previous EFSA opinion on antibiotic resistance marker genes, and no new information on the safety of *npt*II gene as present in the GM potato EH92-527-1 has been identified in the scientific literature that would cause the GMO Panel to change its previous conclusions. Therefore, the EFSA GMO Panel concludes that no grounds exist to date that would lead to reconsideration of its opinion on GM potato EH92-527-1.

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

6.6 Scientific Opinion on an application (EFSA-GMO-NL-2012-107) for the placing on the market of maize MON 810 pollen under Regulation (EC) No 1829/2003 from Monsanto (EFSA-GMO-NL-2012-107)

In this opinion, the EFSA GMO Panel addresses the safety of maize MON 810 pollen to complete the scope of an application (RX-MON 810) for the marketing of genetically modified maize MON 810 with the use of MON 810 pollen as or in food. Data on molecular characterisation of maize MON 810 did not raise any safety concerns with respect to its pollen. The EFSA GMO Panel has previously assessed the safety of the newly expressed Cry1Ab protein in maize MON 810. The assessment and conclusions of the GMO Panel on the safety of this protein, including its potential toxicity and allergenicity, also apply to the Cry1Ab protein expressed in MON 810 pollen. While the EFSA GMO Panel is not in a position to conclude on the safety of maize pollen in or as food in general, it concludes that the genetic modification in maize MON 810 does not constitute an additional health risk if maize MON 810 pollen is to replace maize pollen from non-GM maize in or as food.

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

6.7 Application for authorization of genetically modified cotton MON15985 and derived food and feed, submitted under Regulation (EC) N° 1829/2003 by Monsanto (EFSA-GMO-UK-2008-57) (EFSA-Q-2008-385)

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

7. New mandates

7.1 Applications under Regulation (EC) No 1829/2003

None.

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

The Chair of the GMO Panel informed the Panel members about the content of the 58th Scientific Committee Plenary meeting. Items discussed in this meeting included: the EC mandate on endocrine disruptors; the work-programme of the EFSA Scientific Committee

Working Groups; the specialised courses on advanced aspects of risk assessment; the draft opinion on new challenges for risk assessment; the mandate on environmental risk assessment.

8.2 Working Groups

- **Immunological adjuvant effects in the analysis of interactions in stacked events**

The GMO Panel discussed the adjuvant effect of Cry proteins in allergic reactions. In the case of stacked events that express several Cry proteins, the allergenicity assessment should also address the possible interactions between the Cry proteins and their consequences, if any, from the adjuvanticity point of view.

- Protein expression in pollen

The GMO Panel discussed the potential usefulness of protein expression data from pollen during the risk assessment. It was concluded that such data would be needed, depending on several aspects, such as the scope of the application and the nature of the newly expressed protein(s) of the GM plant in question.

8.3 EFSA

- **Séralini et al. (2012) paper**

The Head of EFSA's Scientific Evaluation of Regulated Products Directorate, Per Bergman, informed the GMO Panel that EFSA had delivered its final evaluation of the paper by Séralini et al. (2012) which raised concerns about the potential toxicity of genetically modified (GM) maize NK603 and of a herbicide containing glyphosate. EFSA's final review reaffirmed its initial assessment that the authors' conclusions cannot be regarded as scientifically sound because of inadequacies in the design, reporting and analysis of the study as outlined in the paper. Consequently, it was not possible to draw valid conclusions about the occurrence of tumours in the rats tested. Based on the information published by Séralini *et al*., EFSA found there was no need to re-examine its previous safety evaluations of NK603 or to consider these findings in the ongoing assessment of glyphosate.

- **Presentation on Specialised courses on advanced aspects of risk assessment**

A member of the EFSA SCOM Unit presented to the GMO Panel a series of courses on advanced aspects of risk assessment. The courses address the following topics: evidence base for risk assessment; variability and uncertainty; exposure assessment.

- **Systematic review courses**

A member of the EFSA SAS Unit presented to the GMO Panel the course on literature systematic review.

- **Presentation on Document and Quality Management**

A member of the EFSA EXO Unit presented to the GMO Panel the implementation of quality management and document management systems in EFSA. The presentation included a description of the systems' components and the benefits of their implementation.

8.4 European Commission

- **Update on draft FF Regulation status**

- **Possible generic mandates**

9. Other scientific topics for information and/or discussion

None.

10. Any other business

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

None.

b) Calendar of plenary meetings for 2014

The Panel members were informed on the dates of the GMO Panel plenary meetings for 2014.

c) Feedback from EFSA10 year anniversary scientific conference (7–8 November 2012, Parma)

The GMO Panel members that had attended the meeting shared their views on the high quality of the event and suggested that such conference should be organised more often.

d) Feedback from the EuropaBio Workshop (24-25 October 2012, Brussels)

The discussions in this meeting focused aspects of the toxicological and allergenicity assessment, including: detailed description of protocols for toxicological studies; compositional analysis for allergens; adjuvant effect in allergic reactions of newly expressed proteins.

e) Feedback from COGEM–EFSA NTO Workshop (29–30 November 2012, Amsterdam)

The workshop organised by EFSA and the Netherlands Commission on Genetic Modification (COGEM) on the effects of *Bt* proteins on non-target organisms (NTOs) was divided in six sessions, as follows: specificity of and interactions between Bt proteins; selection of species for NTO risk assessment; laboratory studies with NTOs; field experiments with NTOs; challenges in NTO risk assessment; workshop lessons, shared views and remaining questions.

f) Feedback from teleconference EFSA - Argentina (23 November 2012, Parma)

This meeting was used to exchange views and to compare approaches for the risk assessment, between EFSA and the GMO Safety Assessment Bodies of the Ministry of Agriculture, Livestock and Fisheries of Argentina. The main topics of the discussion were: field trial design; animal feeding studies; insect management strategies in the case of insect-resistant GM crops cultivation.

g) Feedback from the EFSA – non-governmental organisations (NGO) meeting (27 November 2012, Parma)

During this meeting, items such as the EFSA Guidance on environmental risk assessment of GM animals, herbicide-tolerant crops and target herbicides, the approval process for herbicides and genetically modified herbicide-tolerant plant evaluation, were discussed.

h) GRACE stakeholder meeting (4-5 December 2012, Vienna)

GRACE is a project of the Seventh Framework Programme of the European Commission. The GRACE consortium organised a stakeholder meeting aimed at discussing and improving draft protocols for the design, conduct and analysis of the 90-day animal feeding trials which would be conducted with GM maize and GM potato, as well as the choice and designs of *in vitro* studies.

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.

Annex I

INTERESTS AND ACTIONS RESULTING FROM THE SCREENING OF ADOI OR SDOI

CONFLICT OF INTEREST: In his SDoI, **MR. CHRISTOPH TEBBE** declared the following interest: ***THE APPLICANT COMPANY FOR THE AMFLORA POTATO, BASF, HAD PREVIOUSLY COMMISSIONED A STUDY ON POTATO BY THE EXPERT'S INSTITUTE AND IN WHICH THE EXPERT PARTICIPATED.*** 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, and taking into account the specific matters discussed at the meeting in question, the interest above was deemed to represent a conflict of interest. This results in the inadmissibility for the expert to be present when agenda items 6.4 and 6.5 are discussed, voted on or in anyway processed by that scientific group concerned.

In his SDoI, **MR. ACHIM GATHMANN** declared the following interest: ***IN THE FRAME OF HIS EMPLOYMENT, THE EXPERT HAS OFFICIALLY COMMENTED THE AMFLORA PMEM REPORT AS REPRESENTATIVE OF GERMANY AND SIGNED THE REPORT OF THE GERMAN COMPETENT AUTHORITY AS PART OF HIS EMPLOYMENT.*** 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, and taking into account the specific matters discussed at the meeting in question, the interest above was deemed to represent a conflict of interest. This results in the inadmissibility for the expert to be present when agenda item 6.4 is discussed, voted on or in anyway processed by that scientific group concerned.