MINUTES OF THE 38TH PLENARY MEETING OF THE SCIENTIFIC PANEL ON GENETICALLY MODIFIED ORGANISMS HELD ON 18-19 DECEMBER 2007 IN PARMA, ITALY (ADOPTED ON 30 JANUARY 2008)

AGENDA

PARTICIPANTS

GMO Panel:
Hans Christer Andersson, Salvatore Arpaia, Detlef Bartsch[1], Niels Bohse Hendriksen, Josep Casacuberta, Sirpa Kärenlampi, Jozsef Kiss[1], Ilona Kryspin-Sorensen[1], Harry Kuiper (Chair), Ingolf Nes, Joe Perry, Joachim Schiemann, Willem Seinen, Jeremy Sweet and Jean-Michel Wal.

EFSA:
GMO Unit: Anna Christodoulidou, Zoltan Diveki, Sylvie Mestdagh, Claudia Paoletti, Reinhilde Schoonjans and Ellen Van Haver.

[1] Present only on 18th December 2007.

European Commission:
Sébastien Goux and Sabine Pelsser (DG SANCO).

APOLOGIES

GMO Panel:
Howard Davies, Marc De Loose, Lieve Herman, Nickolas Panopoulos and Annette Pöting.

---

1. WELCOME AND APOLOGIES FOR ABSENCE

The Chair opened the meeting and welcomed all. Apologies for absence were received from some Panel members as mentioned above.

2. ADOPTION OF THE AGENDA

The agenda was adopted as proposed.

3. DECLARATION OF INTERESTS

Panel members were invited to declare possible interests on topics included on the agenda. No specific declarations of interest were declared.

4. ADOPTION OF THE MINUTES OF THE 37TH PLENARY MEETING HELD ON 22-23 NOVEMBER 2007

The minutes of the 37th plenary meeting (22-23 November 2007) were adopted as proposed and will be published at:

http://www.efsa.europa.eu/EFSA/efsa_locale-1178620753812_1178636421388.htm.

5. DISCUSSION AND POSSIBLE ADOPTION OF OPINIONS ON:

5.1. T45 oilseed rape (application EFSA-GMO-UK-2005-25) under Regulation (EC) 1829/2003)

Following the request from the Panel to the applicant for clarification on the compositional data of field trials in the application, the applicant sent an answer which needs to be further scrutinized at the next Food/Feed Working Group meeting. The adoption of the opinion was therefore deferred to the next plenary meeting.

6. NEW REQUESTS TO EFSA: DISCUSSION AND ADOPTION OF MANDATES

6.1. Applications under Regulation (EC) 1829/2003

EFSA received, via the UK, three new applications (UK-2007-48: MIR604 x GA21 Maize; UK-2007-49: Bt11 x GA21 Maize; UK-2007-50: Bt11 x MIR604 Maize) within the framework of Regulation (EC) No 1829/2003 for an overall opinion including the scientific opinion on the respective GMO for import and processing, food and feed use.

Nominated risk assessment bodies of the Member States and national competent authorities within the meaning of Directive 2001/18/EC as foreseen by Articles 6 (4) and 18 (4) of Regulation (EC) No 1829/2003 will be consulted by EFSA once the above mentioned applications are valid. These comments will be considered during the scientific risk assessment of the application by the EFSA GMO Panel.

The summary of these applications, as well as the information on their current status can be found on the following website:
http://www.efsa.eu.int/science/gmo/gm_ff_applications/catindex_en.html.

7. UPDATE ON SELF TASKING ACTIVITIES AND GUIDANCE ON GMO RISK ASSESSMENT

7.1. New self-tasking activity for assessing the impacts of GM plants on non-target organisms

The Panel has drafted a mandate for establishing a self-tasking activity in order to supplement the existing EFSA guidance document for the risk assessment of GM plants and derived food and feed with criteria for assessing the impacts of GM plants on non-target organisms (NTOs), for non-target species selection and for developing standardised testing methodology.

Assessing impacts of GM plants and their cultivation on NTOs is a requirement in current EU regulatory texts. Potential effects on NTOs, mostly arthropods, need to be assessed as part of the Environmental Risk Assessment (ERA) that takes place prior to the commercial cultivation of any GM crop. While there is internationally agreement on some general criteria for conducting the ERA of GM plants, there are also differences in proposed approaches for assessing risks to NTOs. In addition, there remains a need for detailed descriptions of NTO risk assessment procedures including selection criteria for the NTO test species, and test methods that can apply to different regions.

The draft mandate was adopted by the Panel and will be submitted to the EFSA hierarchy for approval.

7.2. EC guidelines and update EFSA guidance document

EFSA, the Commission (DG SANCO) and some Panel members representing the three standing working groups of the GMO Panel (molecular characterisation, food/feed safety and environmental risk assessment) met on 17 December in Parma to discuss the way forward to proceed with the guidelines for the risk assessment that the EC plans to implement (see also item 10 of the minutes of the 37th plenary meeting). It was concluded from that meeting that only one detailed guidance would be optimal to applicants and the existing EFSA Guidance Document was proposed to be used

as a starting point. Some members of the standing working groups of the GMO Panel will start identifying issues in the EFSA guidance document that could be further elaborated and clarified taking into account scientific progress in that field.

8. FEEDBACK FROM EFSA AND THE SCIENTIFIC COMMITTEE

Herman Koëter, Director of Science and Deputy to the Executive Director, discussed with the Panel (1) concerns the Panel has related to its working procedures, such as the high workload and work from home which is not backed-up by financial support, and (2) the wish of the GMO Panel to be involved in EFSA correspondences, when this concerns scientific activities of the GMO Panel.

EFSA organised a workshop with applicants on 13 December 2007 to discuss questions that are raised during the completeness check and the risk assessment of GMO applications. The EFSA GMO Unit discussed with the applicants some possible improvements in the presentation of the data in the GMO applications.

9. DATES OF FUTURE MEETINGS

Meeting dates were agreed at earlier plenary meetings.

10. ANY OTHER BUSINESS

The Panel became aware of the open letter from the European Federation of Biotechnology to Commissioner Dimas (dated 28 November 2007) stating that scientific arguments used by DG ENV as a basis for draft decisions regarding the cultivation of Bt11 and 1507 maize have not been reviewed by EFSA. Considering one of the main goals of EFSA to stay at the forefront of the scientific debate on any kind of topics related to food, feed and environmental safety, the GMO Panel has considered all scientific papers on Bt maize supportive to the draft decisions to see whether they impact on the risk assessment of current and future Bt maize applications[2]. The Panel is not aware of any scientific data which require a re-assessment of Bt maize applications or amendment of previous scientific opinions on the safety of Bt maize.

[2] See also item 12.2 of the minutes of the 37th plenary meeting for the analysis by the GMO Panel of one of these publications (Rosi-Marshall et al., 2007).