MINUTES OF THE 13TH PLENARY MEETING OF THE SCIENTIFIC PANEL ON GENETICALLY MODIFIED ORGANISMS HELD ON 23-24 SEPTEMBER 2004 (ADOPTED ON 20 OCTOBER 2004)

AGENDA

PARTICIPANTS

GMO Panel:
Hans Christer Andersson, Detlef Bartsch[1], Hans-Joerg Buhk, Niels Hendriksen, Sirpa Kärenlampi, Ilona Kryspin-Sorensen, Harry Kuiper (Chair), Marco Nuti, Fergal O'Gara (Vice-Chair), George Sakellaris, Joachim Schiemann[2], Willem Seinen, Jeremy Sweet (Vice-Chair), Jan Dirk Van Elsas and Jean-Michel Wal[3].

Ad Hoc experts[4]:

Tony Hardy (PPR Panel), Richard Phipps (University of Reading).

EFSA:
Anna Christodoulidou (scientific officer), Suzy Renckens (scientific co-ordinator GMO Panel), Markus Röver (scientific officer), Ellen Van Haver (assistant scientific co-ordinator GMO Panel)

European Commission:

Michael Walsh (DG SANCO D5 – Interface Unit)

APOLOGIES

GMO Panel:
Howard Davies, Marc De Loose, Michael Gasson, Pere Puigdomenech Rosell, Angela Sessitsch

---

1. WELCOME AND APOLOGIES FOR ABSENCE

The Chairman 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. Declarations of interests with regard to GM maize 1507 and GM maize Bt11 applications were noted during the 10th Plenary meeting:

---

[1] Only present on 24 September

[2] Not present on 23 September morning

[3] Not present on 24 September afternoon

[4] Invited for agenda item 6.1

http://www.efsa.eu.int/science/gmo/gmo_meetings/388/minutes_gmo_10_en1.pdf

No interests were declared for the other agenda items.

4. ADOPTION OF THE MINUTES OF THE 12TH PLENARY MEETING HELD ON 7-8 JULY 2004

The minutes of the 12th plenary meeting (7-8 July 2004) were adopted. The minutes of this meeting are published at:

http://www.efsa.eu.int/science/gmo/gmo_meetings/490/gmo_minutes_7_8july_en1.pdf

5. CHANGE IN THE GMO PANEL

The GMO Panel was informed about the resignation of one of its members, Prof. Colin Hill. To replace him, a new member, Dr. John Heritage from the University of Leeds, was appointed and approved by the Management Board (meeting of 14 September 2004).

6. DISCUSSION AND POSSIBLE ADOPTION OF OPINIONS ON:

6.1. Question from Commission regarding guidance for GM food and feed applications under Regulation (EC) 1829/2003: Guidance for GM plants and derived food/feed

Introduction

In accordance with Articles 5(8) and 17(8) of the Regulation (EC) 1829/2003 on genetically modified food and feed, the European Commission has requested the European Food Safety Authority (EFSA) to publish detailed guidance to assist the applicant in the preparation and presentation of the application for authorisation of GM food and/or feed (question No EFSA-Q-2003-005).

The GMO Panel prepared a draft guidance document on GM plants and derived food and feed that was published on the EFSA website on 7 April 2004. Interested parties could submit written comments through an on-line consultation process until 9 May 2004. A Stakeholder Consultation was held on 25 May 2004 during which the GMO Panel presented its approach on the risk assessment of GM plants and derived food and feed (see the minutes from the 11th Plenary meeting: http://www.efsa.eu.int/science/gmo/gmo_meetings/457/minutes_gmo_011_en1.pdf).

Discussion

The Panel carefully considered all comments received after the draft guidance document was published on the EFSA website for public consultation, as well as the comments given by participants at the stakeholder consultation held on 25 May in Brussels. The Panel wants to express its gratitude towards all interested stakeholders for the many useful suggestions and is of the opinion that these comments have substantially improved the quality of the document.

A revised version was presented to the Panel members during the Plenary meeting. Some editorial changes and suggestions for clarification were discussed. The Panel agreed on the overall content of the guidance document. Regarding Section 11.4 on general surveillance of the impact of the GM

plant, the Panel felt that this section should be further elaborated and completed after further consultation with stakeholders and in the light of ongoing international discussions. The draft document on general surveillance will be made available on the EFSA website for consultation in due time.

Adoption

The guidance document was adopted by the Panel by consensus. There were no minority opinions. As agreed on 25 May, EFSA will send an advance copy of the guidance document to the participants of the stakeholder consultation meeting. The guidance document will be published on the EFSA website at:

http://www.efsa.eu.int/science/gmo/gmo_guidance/660_en.html

6.2. Question from Commission regarding GM maize 1507 (application C/NL/00/10 under 2001/18)

Introduction

The GMO Panel was tasked to provide a risk assessment of 1507 maize, genetically modified to provide protection against specific lepidopteran pests and tolerance to the herbicide glufosinate. The risk assessment is based on a request from the Commission for a scientific opinion on 1507 maize (notification C/NL/00/10) introduced under Directive 2001/18/EC (EFSA-Q-2004-011). The scope of the application is import, processing and feed use.

EFSA received three different applications for GM maize 1507 (two under Directive 2001/18/EC and one under Regulation (EC) 1829/2003). On request of the GMO Panel, EFSA sent a letter to the Commission clarifying that, for scientific reasons, it is not appropriate to issue an opinion on feed use, import and processing before the complete assessment on food **and** feed matters is finalised. (see minutes of 12th Plenary meeting http://www.efsa.eu.int/science/gmo/gmo_meetings/490/gmo_minutes_7_8july_en1.pdf). The Commission responded that the 1507-application under Directive 2001/18/EC should be treated as 'stand alone' applications in line with the statutory deadlines. This requires an EFSA opinion in terms of feed use only (for the C/NL/00/10-application) during the remainder of the transition period (as laid down in Article 46(3) of Regulation (EC) 1829/2003).

The GMO Panel set up 3 working groups (WG) to examine the application: one WG dealt with the molecular characterisation of the GMO, one WG dealt with food and feed issues (comparative analysis, toxicology and allergenicity) and the third WG studied the environmental aspects related to the proposed uses of GM 1507 maize.

In its evaluation the Panel focused in particular on the issues that were raised by Member States during their initial assessment of the application introduced under 2001/18/EC. The assessment is based on the information provided in the application including additional information from the applicant in reply to questions from Member States and from EFSA.

Discussion

The draft opinion was presented to the Panel members during the plenary meeting. Although all members agreed on the overall content of the opinion, some editorial changes and suggestions for clarification were discussed.

As a main conclusion the opinion states that:

Maize line 1507 has been developed for protection against lepidopteran pests by expressing the CRY1F Protein and for tolerance to glufosinate by the introduction of a *pat* gene from *Streptomyces viridochromogenes*. The GMO Panel has assessed information provided on molecular inserts within the transgenic event, on the safety of the proteins expressed and on the potential for risks associated with any changes to the nutritional, toxicological and allergenic properties of 1507 maize. Analysis of the chemical composition of the maize and field trial data were also used to assess the potential for changes to safety, nutritional as well as agronomic parameters. No data has emerged to indicate that maize line 1507 is any less safe than its non-GM comparators. The EFSA GMO Panel is therefore of the opinion that there is no evidence to indicate that the placing on the market of maize line 1507 and derived products is likely to cause adverse effects on human and animal health and the environment in the context of its proposed use.

The GMO panel is of the opinion that a strict separation of the GMO seeds between food and feed chain uses is extremely unlikely. For this reason no single authorisation should be considered unless aspects of both food and feed safety are authorised.

Adoption

The opinion was adopted by consensus. There were no minority opinions. The opinion will be published on the EFSA website at:
http://www.efsa.eu.int/science/gmo/gmo_opinions/663/gmo_opinion06_ef124_maize1507_en1.pdf.

7. PROGRESS REPORTS ON:

7.1. Question from Commission regarding GM maize Bt11 (application C/FR/96/05/10 under 2001/18/EC)

The GMO Panel is awaiting some clarification from the applicant.

7.2. Question from Commission regarding GM maize 1507 (application C/ES/01/01 under 2001/18/EC)

This application will be discussed at the next working group meeting.

7.3. Question from Commission regarding guidance for GM food and feed applications under Regulation (EC) 1829/2003: Guidance on GM food/feed containing GMM

A working group meeting will be scheduled for the further elaboration of the guidance document on GM food/feed containing GMM.

7.4. Self tasking activity Post market environmental monitoring

This item was deferred to the next plenary meeting.

8. APPLICATIONS RECEIVED UNDER REGULATION 1829/2003

EFSA received four applications via the UK, the Netherlands and Germany within the framework of Regulation (EC) 1829/2003 so far.

New applications:
EFSA-GMO-UK-2004-01 GM maize NK603 x MON810: under completeness check
EFSA-GMO-UK-2004-04 GM rice LLRICE62: under completeness check

Transformed applications:
EFSA-GMO-NL-2004-02 GM maize 1507 (former 258/97 application): consultation Member States has started on 3 September 2004.
EFSA-GMO-DE-2004-03 GM maize MON863 x MON810: under completeness check

9. APPOINTMENT OF RAPPORTEURS FOR NEW QUESTIONS

Rapporteurs have been appointed for the new applications as mentioned under item 8.

10. NEW SELF TASKING ON ANIMAL FEEDING TRIALS

The Panel proposed to have a self tasking activity on the use of animal feeding trials for the safety evaluation of whole GM food/feed. More specifically, the Panel will look at the limitations and potentialities of animal feeding studies for the safety evaluation of whole foods/feed. A background document, the mandate as well as an indication of the timeframe for this activity will be submitted to the EFSA Executive Director for approval.

11. GM-RELATED QUESTIONS TO FEEDAP PANEL

A member of the GMO Panel attended a FEEDAP working group meeting to assess the genetic modification aspects of a GM micro-organism used for the production of a new feed enzyme, submitted in accordance with article 4 of Council Directive 70/524/EEC. For the future, it would be preferable that for such applications the GMO Panel would be involved in the assessment of the genetic modification aspects.

12. GENERAL INFORMATION FROM EFSA

12.1. Feedback from the Scientific Committee

The chair gave an overview of the outcome of the 8th Plenary meeting of the EFSA Scientific Committee held on 28 July 2004 in Parma. The minutes of this meeting are published at: http://www.efsa.eu.int/science/sc_commitee/sc_meetings/517/sc_meet08_minutes_en1.pdf.

In relation to the establishment of the future EFSA Scientific Expert Services, the chair asked the Panel to reflect in which areas and to which extent the Scientific Expert Services could support the GMO Panel.

12.2. EFSA Scientific colloquia

The Panel was informed about the next EFSA scientific colloquium to be held on 13 and 14 December 2004 on "Micro-organisms in Food and Feed, Qualified Presumption of Safety (QPS)". More information can be found on:
http://www.efsa.eu.int/science/colloquium_series/no2_qps/610_en.html.

13. DATE AND PLACE OF FUTURE MEETINGS

A proposal for new dates for future meetings will be sent around to the Panel members after the plenary meeting.

14. ANY OTHER BUSINESS

The chair of the GMO Panel received a letter from the chairman of the Advisory Committee on Releases to the Environment (ACRE) regarding the scientific safety assessment of GM hybrids, and in this regard the safety of the MON 863 x MON 810, on which the Panel delivered an opinion on 2 April 2004. A reply by the chair of the GMO Panel was sent to the chairman of ACRE.

The Panel was also informed about a letter EFSA received from the Food Standards Agency (UK) regarding EFSA's opinion on antibiotic resistance genes as marker genes in genetically modified plants.