European Food Safety Authority

MINUTES OF THE 4TH PLENARY MEETING OF THE SCIENTIFIC PANEL ON GENETICALLY MODIFIED ORGANISMS HELD ON 25 NOVEMBER 2003 (ADOPTED ON 11 DECEMBER 2003)

AGENDA

PARTICIPANTS

GMO Panel:
Hans Christer Andersson, Detlef Bartsch, Hans-Joerg Buhk, Howard Davies, Marc De Loose, Michael Gasson, Niels Hendriksen, Colin Hill, Sirpa Kärenlampi, Ilona Kryspin-Sorensen, Harry Kuiper (Chair), Marco Nuti, Fergal O'Gara (Vice-Chair), Pere Puigdomenech Rosell, George Sakellaris, Joachim Schiemann, Willem Seinen, Angela Sessitsch, Jeremy Sweet (Vice-Chair) and Jean-Michel Wal

EFSA:
Anne-Laure Gassin (Communications Director), Susan Parker (Administrative Secretary GMO Panel), Suzy Renckens (scientific co-ordinator GMO Panel), Ellen Van Haver (assistant scientific co-ordination GMO Panel)

European Commission:
Andreas Klepsch[1] (DG SANCO), Almudena Rodriguez Sanchez-Beato[2] (DG SANCO), Andy Tommey (DG ENV), Michael Walsh (DG SANCO D5 – Interface unit)

[1] Attending afternoon session only.
[2] Attending morning session only.

APOLOGIES

GMO Panel:
Jan Dirk Van Elsas

---

1. WELCOME AND APOLOGIES FOR ABSENCE

The Chairman opened the meeting and welcomed all. Apologies for absence were received from Jan Dirk Van Elsas.

2. ADOPTION OF THE AGENDA

The agenda was adopted as proposed. Because of the urgency of the matter, it was agreed to focus the meeting on 2 questions from the Commission on GM maize NK603. Other subjects that could not be dealt with in detail will be further discussed at the next plenary meeting.

3. DECLARATION OF INTERESTS

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

In relation to the GM maize NK603 applications, listed under agenda item 7.1, possible interests were declared during the plenary meeting of 2 October 2003. The minutes of this meeting are published at: http://www.efsa.eu.int/pdf/minutes_gmo_03_adopted_en.pdf.

4. FEEDBACK FROM THE SCIENTIFIC COMMITTEE

A detailed outline will be given at the next plenary meeting of 11 December 2003.

5. NEW REQUESTS TO GMO PANEL: UPDATE DRAFT WORK PROGRAMME – PRESENTATION AND DISCUSSION OF THE MANDATES

EFSA received from the Commission a request for a scientific opinion on GM maize MON863 and MON863 X MON810 introduced under Directive 2001/18/EC (EFSA-Q-2003-108). It was also noted that an application for the marketing of the same GMOs was introduced within the framework of Regulation (EC) 258/97. An official request was however not yet received.

6. APPOINTMENT OF RAPPORTEURS FOR NEW QUESTIONS

Rapporteurs have been appointed for the new questions and meetings of the working groups have been scheduled.

7. DISCUSSION AND POSSIBLE ADOPTION OF OPINIONS ON: 2 QUESTIONS FROM THE COMMISSION ON GM MAIZE NK603 (APPLICATIONS UNDER 258/97 AND 2001/18)

Introduction

The GMO Panel was tasked to provide a risk assessment of NK603 Roundup Ready maize, genetically modified to provide tolerance to the herbicide glyphosate, also known as Roundup, and derived food and feed products. The risk assessment is based on two requests by the Commission related to two applications for the placing on the market of maize NK603 by Monsanto, one under the Novel Food Regulation (EC) No 258/97 and one under the environmental release Directive 2001/18/EC.

The GMO Panel set up 3 working groups (WG) to examine simultaneously both applications: one WG dealt with the molecular characterization 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 the GM maize.

In its evaluation the Panel focused in particular on the issues that were raised by Member States (MS) during their initial assessment of the applications introduced under 258/97 and 2001/18/EC. The assessment is based on the information provided in the 2 applications including additional information from the applicant in reply to MS questions.

Although the Panel will provide 2 separate opinions, as requested by the Commission because both applications were introduced within a different legislative framework, it does not discriminate in its assessment between the 2 applications, except for the environmental release aspect. Therefore, the assessment part of the opinion and the related opinion will be identical.

Discussion

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

As a main conclusion the opinions state that:

- The Panel considered the information made available by the applicant as sufficient to evaluate the safety of NK603 maize and derived products, food and feed ingredients and to address all the specific questions raised by the Member States related to the risk assessment. Therefore additional experimental studies are not deemed necessary.
- The Panel has considered information provided on (1) the molecular inserts within the transgenic event, (2) the chemical composition of the GM and non-GM maize, (3) the safety of the proteins expressed and (4) the potential for risks associated with any changes to the toxicological, allergenic and nutritional properties of NK603. Having considered the evidence, the GMO Panel is of the opinion that NK603 maize is as safe as conventional maize and therefore the placing on the market of NK603 maize for food or feed or processing is unlikely to have an adverse effect on human and animal health and, in that context, the environment.

Adoption

The opinions were adopted by the Panel by consensus. There were no minority opinions. The opinions will be published on the EFSA website at: http://www.efsa.eu.int/p_gmo_en.html

Press briefing

The Communication Director from EFSA informed the Panel that EFSA intended to have a press briefing and press release on the opinion on 4 December 2003 as this was the first opinion on a GMO application to be issued by EFSA. The opinion will be accompanied by a summary that will be translated to German and French for publication on the website.

8. PROGRESS REPORT ON:

8.1. Question from Commission regarding GMM guidelines for contained use

EFSA received a request (EFSA-Q-2003-004) to provide a scientific opinion on the draft Annex "Guidance notes supplementing Part B of Annex II to Directive 90/219/EEC on the contained use of genetically modified micro-organisms" (see the minutes of the previous plenary meeting: http://www.efsa.eu.int/pdf/minutes_gmo_03_adopted_en.pdf).

A working group was set up to deal with this specific request. A draft opinion was distributed to the Panel members. A more detailed discussion of the draft opinion will take place at the next plenary meeting.

8.2. Self tasking activity on antibiotic resistance markers

A revised document on the antibiotic resistance genes was distributed during the meeting. A meeting of the working was scheduled for 26 November 2003. This issue will be further discussed at the next plenary meeting.

8.3. Question from Commission regarding guidance for GM food and feed applications under Regulation (EC) 1829/2003

This item was deferred to the next plenary meeting because of the limited timeframe.

8.4. Terms of reference for self tasking activities

The background and the terms of reference of the following new proposals for self tasking were distributed to the members of the Panel. The documents will be discussed at a next plenary meeting.

- Impact of GMOs on microbial biodiversity and function in the soil environment
- Post market monitoring of crops
- Assessment of allergenicity of genetically modified (GM) foods
- Post market surveillance of genetically modified (GM) foods
- Safety of use of viral promoters and specifically of the cauliflower mosaic virus (CaMV) promoter.