



**MINUTES OF THE 25TH PLENARY MEETING OF THE
SCIENTIFIC PANEL ON GENETICALLY MODIFIED ORGANISMS
HELD ON 28-29 MARCH 2006
(ADOPTED ON 16 MAY 2006)**

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PARTICIPANTS

GMO Panel:

Hans Christer Andersson, Detlef Bartsch, Hans-Joerg Buhk¹, Howard Davies, Marc De Loose, Niels Bohse Hendriksen, John Heritage, Sirpa Kärenlampi, Ilona Kryspin-Sorensen, Harry Kuiper (Chair), Marco Nuti², Fergal O’Gara (Vice-Chair), Pere Puigdomenech, George Sakellaris, Joachim Schiemann, Willem Seinen, Jeremy Sweet (Vice-Chair), and Jean-Michel Wal.

EFSA:

David Carlander (scientific officer), Anna Christodoulidou (scientific officer), Karine Lheureux (scientific officer), Luisa Mannu (scientific officer), Sylvie Mestdagh (scientific officer), Claudia Paoletti (scientific officer), Suzy Renckens (scientific co-ordinator GMO Panel), Reinhilde Schoonjans (scientific officer), Ellen Van Haver (assistant scientific co-ordinator GMO Panel).

European Commission:

Sébastien Goux (DG SANCO).

APOLOGIES

GMO Panel:

Mike Gasson, Angela Sessitsch and Jan Dick Van Elsas.

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 applications already announced during previous Plenary meetings are noted in the corresponding minutes.

As regards new applications (UK-2006-34 GM maize 3272), some members³ indicated that they had been or in the future may be to some extent involved in the safety assessment process of these applications at national level and provided a written declaration. It was decided from these

¹ Only present 29 March 2006

² Only present 28 March 2006

³ Detlef Bartsch, Hans-Jörg Buhk and Joachim Schiemann.

declarations that there was no conflict of interest and that the involvement in the national safety assessment process did not compromise the assessment of applications by EFSA.

4. ADOPTION OF THE MINUTES OF THE 24TH PLENARY MEETING HELD ON 24-25 JANUARY 2006

The minutes of the 24th plenary meeting (24-25 January 2006) were adopted as proposed. The minutes of this meeting are published at:

http://www.efsa.eu.int/science/gmo/gmo_meetings/1313_en.html

5. FEEDBACK FROM EFSA AND THE SCIENTIFIC COMMITTEE

The Panel was informed about the outcome of the 17th Plenary meeting of the Scientific Committee held on 15-16 February 2006. The minutes of this meeting are published at:

http://www.efsa.eu.int/science/sc_committee/sc_meetings/1344_en.html

6. FEEDBACK FROM THE COMMISSION

Following an earlier request from the Commission for scientific advice on a proposed draft guideline from the Codex Ad hoc Intergovernmental Task Force (see minutes of 24th Plenary meeting), EFSA has been asked to provide comments to the Commission on the draft guidance documents prepared by the Codex in the area of recombinant-DNA animals and recombinant-DNA plants modified for nutritional or health benefits. In addition, EFSA has been asked by the Commission for a continued participation in the work of the Task Force, and that a representative of EFSA would take part in the EC delegation.

7. DISCUSSION AND POSSIBLE ADOPTION OF OPINIONS ON:

7.1. 1507 x NK603 maize (EFSA/GMO/UK/2004/05 under Regulation 1829/2003)

Introduction

The GMO Panel was requested, in accordance with Articles 6(6) and 18(6) of Regulation (EC) No 1829/2003, to carry out a scientific assessment of genetically modified maize 1507 x NK603 for food and feed uses, import and processing.

The opinion of the GMO Panel corresponds to the safety assessment report as referred to in Articles 6(6) and 18(6) of Regulation (EC) No 1829/2003 and will be part of the overall EFSA opinion as required by Articles 6(5) and 18(5) of Regulation (EC) No 1829/2003.

Discussion

The assessment is based on the information provided in the application, including additional information from the applicant in reply to questions from Members States (MS) and from EFSA.

The draft opinion was presented to the Panel members during the plenary meeting followed by a discussion on outstanding issues.

As a main conclusion, the opinion states that:

The Panel assessed maize 1507 x NK603, which is produced by a cross between inbred lines of maize containing the 1507 and NK603 events, for food and feed uses, import and processing. Maize 1507 and maize NK603 were evaluated previously. Both maize NK603 and maize 1507 have been authorized by the European Commission. In assessing the maize 1507 x NK603, both the single events and the maize 1507 x NK603 were considered. The Panel concluded that it was acceptable to use data for the single events 1507 and NK603 in support of the safety assessment of the maize 1507 x NK603 and that the information available for maize 1507 x NK603 addresses the scientific issues raised by the Member States.

The Panel considers that the maize 1507 x NK603 is as safe as its conventional counterparts with respect to effects on human and animal health and the environment and therefore concludes that this maize is unlikely to have any adverse effect on human and animal health and the environment in the context of its intended uses.

Adoption

The opinion was adopted unanimously by the Panel. The opinion can be found on the EFSA website at:

http://www.efsa.eu.int/science/gmo/gmo_opinions/1482_en.html

7.2. Risk Assessment of Plants Containing Genetic Modification Events Combined by Crossing

A draft document on the risk assessment of plants containing GM events combined by crossing was presented to the Panel. The Panel had some suggestions for scientific improvement and discussed about the format of the publication of this document.

The Panel had also some discussion about the legal background and the status of plants containing GM events combined by crossing within the framework of Directive 2001/18/EC. The aim of the document is however to deal with the scientific technical details for the risk assessment of such plants and not with the legal aspects.

7.3. Guidance document for the risk assessment of GMMs and derived food and feed

The draft guidance document for the risk assessment of GMMs and derived food and feed was presented to the Panel. As the Commission and EFSA had to discuss further the legal background as laid down in the document, the adoption of the whole document was postponed and the Panel agreed on the scientific part dealing with the risk assessment of GMMs and derived food and feed. The remaining part of the document was referred to the next plenary meeting for adoption.

7.4. Natuphos – 3Phytase, E 1600 (FAD-2005-0008)

The discussion on this application was referred to the next plenary meeting.

7.5. Safeguard clauses invoked under article 16 of Directive 90/220/EEC

Introduction

EFSA received from the Commission a request, under Article 29(1) and in accordance with Article 22(5)(c) of Regulation (EC) No 178/2002, to provide a scientific opinion, as to whether there is any scientific reason to believe that the continued placing on the market of the genetically modified crops Bt176 maize, MON810 maize, T25 maize, Topas 19/2 oilseed rape and Ms1xRf1 oilseed rape (which are subject to the safeguard clauses), are likely to cause any adverse effects for human health or the environment under the conditions of consent. In particular, EFSA was requested to answer specific questions on the basis of generally available scientific data and earlier assessments but EFSA was not in a position to comment on the quality of the earlier applications or their compliance with the current legislation.

Discussion

The draft opinion on the safeguard clauses was presented to the Panel and some editorial and suggestions for clarification were discussed.

As a main conclusion the opinion states that:

The GMO Panel is of the opinion, that, with respect to the specific questions raised by the European Commission, and on the basis of current scientific knowledge, there is no reason to believe that the continued placing on the market of Bt176, T25 and MON810 maize, and Ms1xRf1 and Topas 19/2 oilseed rape (which are subject to safeguard clauses) is likely to cause adverse effects for human and animal health or the environment under the conditions of their respective consents.

Adoption

The opinion was adopted unanimously by the Panel. The opinion can be found on the EFSA website at:

http://www.efsa.eu.int/science/gmo/gmo_opinions/1439_en.html

8. OPINIONS ADOPTED BY WRITTEN PROCEDURE:

The Panel adopted on 28 February 2006 by written procedure the co-opinions of the FEEDAP and of the GMO Panel on the safety and efficacy of the enzyme preparations **Phytase SP 1002 (3-phytase)** for use as feed additive for piglets, pigs for fattening, sows, chickens for fattening, turkeys and laying hens (Question No EFSA-Q-2005-030) and **Phyzyme XP (6-Phytase)** for use as feed additive for chickens for fattening (Question No EFSA-Q-2005-063) with regard to the risk assessment of the genetic modification of both applications.

The opinions can be found on the EFSA website at:

http://www.efsa.eu.int/science/feedap/feedap_opinions/1410_en.html
http://www.efsa.eu.int/science/feedap/feedap_opinions/1468_en.html

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

9.1. Application EFSA-GMO-UK-2006-34: 3272 Maize under Regulation 1829/2003

EFSA received, via the UK, one new application (UK-2006-34 GM maize 3272) within the framework of Regulation (EC) No 1829/2003 for an overall opinion including the scientific opinion on GM maize 3272 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 application is valid. These comments will be considered during the scientific risk assessment of the applications by the EFSA GMO Panel.

The summary of this application, as well as the information on its current status can be found on the following website:

http://www.efsa.eu.int/science/gmo/gm_ff_applications/catindex_en.html.

10. UPDATE ON APPLICATIONS RECEIVED UNDER DIRECTIVE 2001/18/EC, REGULATION (EC) 1829/2003 AND REGULATION (EC) 1831/2003

- MIR604 maize (application EFSA-GMO-UK-2005-11 under Regulation (EC) No 1829/2003); summary: http://www.efsa.eu.int/science/gmo/gm_ff_applications/more_info/818_en.html.

The Panel has requested additional information on the molecular characterisation and food/feed safety of MIR604 maize. The clock for this application has been stopped.

11. UPDATE ON SELF TASK ACTIVITIES AND GUIDANCE FOR GMO RISK ASSESSMENT

The draft mandate for a new self tasking activity on statistical considerations for the safety evaluation of GMOs will be circulated to the Panel for adoption by written procedure after the plenary meeting. The Panel will investigate within the framework of this self task whether more detailed guidance could be provided to applicants regarding the performance of field trials and analysis of compositional data using appropriate statistical methods. Moreover, there is a need for a more uniform approach in the set-up of animal feeding trials and analysis of data.

12. STAKEHOLDER ISSUES

EFSA held a technical meeting on 22 February 2006 with NGOs concerning the risk assessment of GMOs. The aim of this meeting was to clarify the role of EFSA in the assessment of GMOs, the basis for its scientific assessments and its risk assessment procedures. EFSA listened to the views of the NGOs on scientific matters. The report of this meeting can be found on the following website:

http://www.efsa.eu.int/stakeholder_stakeholder_consultative_platform/technical_meetings/catindex_en.html

The Panel was informed about the Environmental Council held on 9 March 2006 during which a policy debate on GMOs was held. The orientation debate focused in particular on issues relating to risk management and authorisation procedures. Reference was also made to the need for

coordination between all bodies concerned in particular between the Commission, EFSA and the competent national organisations.

From the meeting with the NGOs and from the Environment Council meeting, EFSA learned that there is a need for further clarification on the process of GMO assessments and the role of EFSA *vis a vis* the Commission and the Member States. EFSA and the GMO Panel will therefore hold a Forum discussion with national experts on the scientific assessment of GMOs in the EU on 15 May 2006 to clarify EFSA's role and to provide opportunity for discussion between national experts and EFSA's scientific expert panel members involved in the risk assessment of GMOs.

13. DATE OF FUTURE MEETINGS

Meeting dates were agreed at an earlier plenary meeting.

14. ANY OTHER BUSINESS

The Panel was informed about an ACRE draft report on risks and benefits of novel agricultural systems that has been published on the ACRE-website for public consultation: <http://www.defra.gov.uk/environment/acre/fsewiderissues/index.htm>.
