European Food Safety Authority

DRAFT MINUTES OF THE 22ND PLENARY MEETING OF THE SCIENTIFIC PANEL ON GENETICALLY MODIFIED ORGANISMS HELD ON 12-13 OCTOBER 2005 (ADOPTED ON 6 DECEMBER 2005)

AGENDA

PARTICIPANTS

GMO Panel:
Hans Christer Andersson, Detlef Bartsch Hans-Joerg Buhk, Howard Davies, Marc De Loose[1], Mike Gasson, Niels Bohse Hendriksen, John Heritage[1], Sirpa Kärenlampi, Ilona Kryspin-Sorensen, Harry Kuiper[1] (Chair), Marco Nuti, Pere Puigdomenech, George Sakellaris, Willem Seinen, Angela Sessitsch, Jeremy Sweet (Vice-Chair), Jan Dick Van Elsas and Jean-Michel Wal.

EFSA:
Anna Christodoulidou (scientific officer), Karine Lheureux (scientific officer), Luisa Mannu (scientific officer), Sylvie Mestdagh (scientific officer), Suzy Renckens (scientific co-ordinator GMO Panel), Ellen Van Haver (assistant scientific co-ordinator GMO Panel).

European Commission:
Michael Walsh (DG SANCO D5 – Interface Unit), Sébastien Goux (DG SANCO), Katja Neubauer[1] (DG SANCO), Ladislav Miko[1] (DG ENV B – Director), Werner Bosmans[1] (DG ENV B).

APOLOGIES

GMO Panel:
Fergal O'Gara (Vice-Chair) and Joachim Schiemann.

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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-2005-20 GM maize 59122 x NK603[2], UK-2005-21 GM maize 59122 x 1507 x NK603[3]), some members indicated that they had been 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 declarations that there was no conflict of interest and that the

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[1] Not present 13 October 2005
[2] GM maize 59122 x NK603: Detlef Bartsch, Hans-Jörg Buhk, Gijs Kleter and Joachim Schiemann.
[3] GM maize 59122 x 1507 x NK603: Detlef Bartsch, Hans-Jörg Buhk, Gijs Kleter and Joachim Schiemann.

involvement in the national safety assessment process did not compromise the assessment of applications by EFSA.

4. ADOPTION OF THE MINUTES OF THE 21ST PLENARY MEETING HELD ON 13-14 SEPTEMBER 2005

The minutes of the 21st plenary meeting (13-14 September 2005) were adopted as proposed. The minutes of this meeting are published at:

http://www.efsa.eu.int/science/gmo/gmo_meetings/1126/gmo_minutes_21st_plenmeet1.pdf

5. FEEDBACK FROM EFSA AND THE SCIENTIFIC COMMITTEE

The EFSA – GMO Unit organised an introductory meeting for new ad hoc experts who will assist the GMO Panel in the risk assessment of applications submitted within the framework of Regulation (EC) 1829/2003 and Directive 2001/18/EC. New ad hoc experts have been invited with expertise in molecular characterisation, food/feed safety and environmental risk assessment of GMOs.

The GMO Panel was informed about the discussions at the September plenary meeting of the Scientific Committee on the operational strategy for expert meetings in Parma, as well as on issues related to the functioning of the Scientific Committee and Scientific Panels (see minutes at http://www.efsa.eu.int/science/sc_commitee/sc_meetings/1132/sc_minutes_14thplenmeet1.pdf).

The GMO Panel was informed about the concerns expressed by Greenpeace and Friends of the Earth at the inaugural EFSA stakeholder consultative platform held on 6&7 October 2005 in Parma. Until now the GMO Panel has held several public consultations and stakeholder consultation meetings (see at http://www.efsa.eu.int/science/gmo/gmo_consultations/catindex_en.html). The Panel will continue to consult stakeholders on new draft guidance documents and within the framework of self task activities.

To make opinions more accessible to non-specialists, the GMO Unit is exploring the possibility/need to provide for some opinions explanatory notes which would be less technical and provide background information on the opinion. A draft explanatory note on the opinion concerning GM oilseed rape MS8xRF3 was distributed to the Panel for comments.

6. FEEDBACK FROM THE COMMISSION

Mr Ladislav Miko, Director from Directorate B from DG Environment attended the GMO Plenary meeting to be informed about the working procedures of the Panel and to discuss with the Panel the fact that Member States fail to reach consensus on GMO matters and more specifically in relation to the proposed lifting of bans or restrictions (so-called national safeguard clauses) on 8 authorised GM products (http://europa.eu.int/rapid/pressReleasesAction.do?reference=IP/05/793&format=HTML&aged=0&language=EN&guiLanguage=en). The Commission is reflecting on how to deal with the Member States concerns and Mr Miko therefore wanted to explore possible ways forward. The main task of the GMO Panel is however to concentrate on the quality of the risk assessment and to address uncertainties from a scientific point of view. The Panel recognises the importance of the interface

between risk assessment and risk management. Stakeholder consultations (see also item 5) are considered a useful tool to explain the science that underpins risk management measures, and will continue to make efforts in the area of stakeholder consultations.

The Commission representative from DG Sanco informed the Panel about the fifth session of the Codex Alimentarius ad hoc intergovernmental Task Force on foods derived from biotechnology (Chiba, Japan, 19 - 23 September 2005), in which the Chairman of the GMO Panel also participated to assist the European Commission with scientific advice on GMO related matters. The Task Force agreed upon the development of guidelines for the conduct of food safety assessment of foods derived from GM animals and for the safety assessment of foods derived from rDNA plants modified for nutritional or health benefits. The GMO Panel will consider how it can provide support to the Commission on these matters.

7. DISCUSSION AND POSSIBLE ADOPTION OF OPINIONS ON:

7.1. NK603 x MON 810 maize (EFSA/GMO/UK/2004/01 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 NK603 x MON 810 for food and feed uses.

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 and adoption

See item 7.2.

7.2. NK603 x MON 810 maize (application C/GB/02/M3/03 under Directive 2001/18/EC)

Introduction

The GMO Panel was requested, 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 placing on the market of NK603 x MON 810 maize for import and processing for feed and industrial uses is likely to cause any adverse effects on human health and the environment within the scope of Directive 2001/18/EC. In particular EFSA was requested to take account of the objections raised by competent authorities of Member States in this context.

Discussion

Item 7.1 was discussed along with item 7.2. Although the Panel will provide 2 separate opinions as both applications were introduced within a different legislative framework, it does not discriminate in its assessment between the 2 applications. Therefore, both opinions will be identical for the related parts.

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

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

As a main conclusion the opinions state that:

The GMO Panel assessed the NK603 x MON810 maize which is produced by crossing between inbred lines of maize containing MON810 and NK603 events. The MON810 and NK603 maize events were evaluated previously and both of them have been authorized for import, processing and food/feed uses. In assessing the NK603 x MON810 maize, both the single insert lines and the NK603 x MON810 maize were considered. The GMO Panel concluded that it was also acceptable to use data derived from the previous assessments of the single events NK603 and MON810 in support of the safety assessment of the NK603 x MON810 maize.

The GMO Panel, in line with the EFSA Guidance document, has assessed the molecular characterisation of the combined traits in NK603 x MON810 together with data on the levels of Cry1Ab and CP4 EPSPS protein expression and compositional analysis. Comparisons on expression were made using the single events MON810 and NK603.

The GMO Panel has reached the opinion that NK603 x MON810 maize is unlikely to have adverse effects on human and animal health. NK603 x MON810 maize is being assessed for import for food and feed uses only and thus there is no requirement for scientific information on environmental effects associated with cultivation. However, The GMO Panel agrees that in the case of any adventitious establishment, any unintended environmental effects due to spread of NK603 x MON810 maize will not be significantly different to that of traditionally bred maize.

In conclusion, the GMO Panel considers that information available for NK603 x MON810 maize addresses the outstanding questions raised by the Member States and considers it unlikely that NK603 x MON810 maize will have any adverse effect on human and animal health or the environment in the context of its proposed uses.

Adoption

The opinions were adopted unanimously by the Panel. The opinions can be found on the EFSA website at:

http://www.efsa.eu.int/science/gmo/gmo_opinions/1284/gmo_op_ej309_maizenk603xmon810_en1.pdf
http://www.efsa.eu.int/science/gmo/gmo_opinions/1283/gmo_op_ej308_maizenl603xmon810_en1.pdf

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

8.1. Application EFSA/GMO/UK/2005/20: 59122 x NK603 maize under Regulation 1829/2003

EFSA received, via the UK, a new application (EFSA-GMO-UK-2005-20) within the framework of Regulation (EC) 1829/2003 for a scientific opinion on GM maize 59122 x NK603 for import and processing, and food and feed use. The summary can be found at: http://www.efsa.eu.int/science/gmo/gm_ff_applications/more_info/1162/summary_efsa_gmo_uk_2005_20-59122xnk6031.pdf.

Nominated risk assessment bodies of Member States and national competent authorities within the meaning of Directive 2001/18/EC as foreseen by Articles 6&18 (4) of Regulation 1829/2003 will be consulted by EFSA once the application is valid. These comments will be considered during the assessment of the application by the GMO Panel.

8.2. Application EFSA/GMO/UK/2005/21: 59122 x 1507 x NK603 maize under Regulation 1829/2003

EFSA received, via the UK, a new application (EFSA-GMO-UK-2005-21) within the framework of Regulation (EC) 1829/2003 for a scientific opinion on GM maize 59122 x 1507 x NK603 for import and processing, and food and feed use. The summary can be found at: http://www.efsa.eu.int/science/gmo/gm_ff_applications/more_info/1163/summary_efsa_gmo_uk_2005_21-59122x1507xnk6031.pdf.

Nominated risk assessment bodies of Member States and national competent authorities within the meaning of Directive 2001/18/EC as foreseen by Articles 6&18 (4) of Regulation 1829/2003 will be consulted by EFSA once the application is valid. These comments will be considered during the assessment of the application by the GMO Panel.

The summary of the 1829/2003-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.

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

- H7-1 Roundup Ready Sugar Beet (application EFSA/GMO/UK/2004/08 under Regulation (EC) 1829/2003; summary: http://www.efsa.eu.int/science/gmo/gm_ff_applications/more_info/741/02partiisummary1.pdf).

  The Panel has requested further clarification from the applicant as regards the compositional analysis of H7-1 Roundup Ready sugarbeet.

- Question from the Commission regarding 281-24-236 x 3006-210-23 cotton (application C/NL/04/01 under Directive 2001/18/EC and EFSA/GMO/NL/2005/16 under Regulation (EC) 1829/2003); summary: http://www.efsa.eu.int/science/gmo/gm_ff_applications/more_info/1026/summary_efsa_gmo_nl_2005_161.pdf).

  The Panel has requested additional information on the molecular characterisation and food/feed safety of 281-24-236 x 3006-210-23 cotton.

- Question from the Commission regarding GM potato EH92-527-1 (application C/SE/96/3501 under Directive 2001/18/EC and application EFSA-GMO-UK-2005-14 under Regulation (EC)

1829/2003; summary: http://www.efsa.eu.int/science/gmo/gm_ff_applications/more_info/909/efsa_gmo_uk_2005_141.pdf).

The applicant sent a reply to the request of the Panel for additional information. The additional information will be assessed at a next working group meeting.

- 1507 x NK603 maize (application EFSA/GMO/GMO/2004/05 under Regulation (EC) 1829/2003; summary: http://www.efsa.eu.int/science/gmo/gm_ff_applications/more_info/650/efsa_gmo_uk_2004_051.pdf).

  The applicant sent a reply to the request of the Panel for additional information. The additional information was assessed by the working group and further clarification was requested from the applicant.

10. UPDATE ON GM FEED ENZYMES APPLICATIONS

The GMO Panel had a discussion on the safety assessment of feed enzymes produced with genetically modified microorganisms following the last Plenary meeting in October during which the Panel formulated some questions regarding the molecular data in two feed enzymes applications (Phytase SP 1002 and Phyzyme XP).

As this is a co-opinion of the FEEDAP and the GMO Panels, the FEEDAP Panel suggested that the presence or absence of the GMM and its DNA should be the first consideration and that further assessment was deemed unnecessary unless the GMM or its DNA remains in the enzyme preparation. The majority of the GMO Panel members is of the opinion that the safety assessment of the GMM has to be evaluated on a case-by-case basis, taking into account the nature of the genetic modification and the presence of the GMM and its DNA in the final enzyme preparation, as described in the draft GMM Guidance document (http://www.efsa.eu.int/science/gmo/gmo_consultations/1035/gmo_consultation_guide_gmm2_en1.pdf). The safety assessment of the end product itself is carried out by the FEEDAP Panel.

11. UPDATE ON SELF TASK ACTIVITIES

11.1. Self tasking activity on animal feeding trials

A follow-up of the fourth working group meeting on the use of animal feeding trials for whole GMO food/feed held on 7 October 2005 was presented to the Panel. A first draft document has been discussed and gaps and overlaps in the document have been identified. The document is intended to focus on GM foods/feed, but will also be applicable to novel/functional foods at large.

11.2. Self tasking activity on post market environmental monitoring

The comments from the public consultation (see item 12) received so far were discussed at the last working group meeting on post market environmental monitoring (PMEM) held on 19 September 2005, as well as the draft opinion addressing more general recommendations on PMEM.

11.3. Self tasking activity on the assessment of GM plants used as production platform for non-food/feed products

Following the proposal from the GMO Panel for a self tasking activity on the assessment of GM plants used as production platform for non-food/feed products, a letter from the EFSA Director of Science was sent to the Panel to support this activity. For this self tasking activity, external experts with expertise in this field will be invited and close collaboration will be sought with other European Agencies (European Medicines Agency) and the Commission.

12. OUTCOME PUBLIC CONSULTATIONS ON THE GMM GUIDANCE DOCUMENT AND ON GENERAL SURVEILLANCE OF THE IMPACT OF GM PLANTS

From 15 July until 30 September 2005, EFSA conducted two public consultations on its website, respectively on the draft guidance document for the risk assessment of genetically modified microorganisms (GMM) and their derived products for food and feed use and on the draft chapter 11.4 of the GM plant guidance document on "General surveillance of the impact of GM plants".

EFSA received comments on the draft document on general surveillance from 29 contributors from EU Competent Authorities, public research institutes, non-governmental organisations and biotechnology associations from 11 countries.

As regards the GMM guidance document, EFSA received written comments from 28 public or private institutions from 13 countries (including EU countries, US, Canada and Japan).

The Panel will consider these comments at the next working group meetings.

13. APPOINTMENT OF RAPPORTEURS FOR NEW QUESTIONS

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

14. DATES OF FUTURE MEETINGS

Meeting dates were agreed at an earlier plenary meeting.

15. ANY OTHER BUSINESS

There were no any other businesses.
