



European Food Safety Authority

MINUTES OF THE 20TH PLENARY MEETING OF THE SCIENTIFIC PANEL ON GENETICALLY MODIFIED ORGANISMS HELD ON 5-6 JULY 2005 (ADOPTED ON 13 SEPTEMBER 2005)

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PARTICIPANTS

GMO Panel:

Hans Christer Andersson, Detlef Bartsch Hans-Joerg Buhk¹, Howard Davies, Marc De Loose, Mike Gasson, Niels Bohse Hendriksen, John Heritage, Sirpa Kärenlampi, Ilona Kryspin-Sorensen, Harry Kuiper (Chair), Pere Puigdomenech, George Sakellaris, Joachim Schiemann, Willem Seinen, Angela Sessitsch, Jeremy Sweet (Vice-Chair), 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), Werner Bosmans (DG ENV B)².

APOLOGIES

GMO Panel:

Marco Nuti, Fergal O’Gara 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 (GM cottonseed 281-24-236/3006-210-23, 1507 x NK603 maize), declaration of interests were already announced during previous meetings in the context of application C/NL/04/01 and application EFSA-GMO-UK-2004-05.

¹ Not present 5 July 2005 am.

² Present 5 July 2005 pm

4. ADOPTION OF THE MINUTES OF THE 19TH PLENARY MEETING HELD ON 8-9 JUNE 2005

The minutes of the 19th plenary meeting (8-9 June 2005) were adopted as proposed. The minutes of this meeting are published at:

http://www.efsa.eu.int/science/gmo/gmo_meetings/949/gmo_minutes_19th_plenmeet1.pdf

5. FEEDBACK FROM AND TO THE SCIENTIFIC COMMITTEE/EFSA

The Chair gave an overview of the outcome of the 13th Plenary meeting of the EFSA Scientific Committee held on 21-22 June 2005. The minutes of this meeting are published at:

http://www.efsa.eu.int/science/sc_committee/sc_meetings/979/sc_minutes_13th_plenmeet1.pdf

6. DISCUSSION AND POSSIBLE ADOPTION OF OPINIONS ON:

6.1. Question from Commission regarding guidance for GM food/feed applications under Regulation 1829/2003: GMM guidance

Introduction

In accordance with Articles 5(8) and 17(8) of the Regulation (EC) N° 1829/2003 on genetically modified food and feed, EFSA has to publish detailed guidance to assist the applicant in the preparation and the presentation of the application for authorisation of GM food and/or feed.

EFSA has already published in November 2004 a first guidance document of the GMO Panel for the risk assessment of GM plants and derived food and feed (http://www.efsa.eu.int/science/gmo/gmo_guidance/660_en.html). The new draft guidance document prepared by the GMO Panel provides detailed guidance for the risk assessment of genetically modified microorganisms (GMMs) and their derived products intended for food and feed use. The guidance covers a broad spectrum of GMMs and derived products ranging from pure compounds used in food or feed (food/feed additives, flavourings, etc.) to viable GMMs used as pure cultures (probiotics, starter cultures). In the guidance document all GMMs and derived products intended for food/feed use are divided into three groups with different levels of scrutiny for the risk assessment.

Discussion and adoption

The rapporteur reported on the progress made during the last meeting of the working group held on 5 July 2005. The draft guidance document was discussed and adopted unanimously by the Panel. The draft document will be published on the EFSA website for a 2 month period of public consultation (http://www.efsa.eu.int/science/gmo/gmo_consultations/1035_en.html). The Panel will consider the written comments received from the public before adoption of a final document.

6.2. New Chapter 11.4 on General surveillance of the impact of GM plants in the “Guidance document for the risk assessment of GM plants and derived food and feed”

Introduction

In accordance with Article 5(8) and 17(8) of Regulation (EC) No 1829/2003 on genetically modified food and feed, EFSA has published detailed guidance to assist the applicant in the preparation and presentation of the application for authorisation of GM food and/or feed (http://www.efsa.eu.int/science/gmo/gmo_guidance/660_en.html).

Chapter 11.4 on “General Surveillance of the impact of GM plants” of the EFSA guidance document of the GMO Panel for the risk assessment of GM plants and derived food and feed was not finalised and was left for further consideration by the GMO Panel. The EFSA working group on PMEM, created in April 2004, organised 6 meetings including a series of three consultation workshops with different stakeholders (applicants, environmental institutes and organisations, experts from Member States; http://www.efsa.eu.int/science/gmo/gmo_consultations/732_en.html).

Discussion and adoption

The new version of chapter 11.4 on “General Surveillance of the impact of GM plants” was discussed and adopted unanimously by the Panel. The draft chapter will be published on the EFSA website for a 2 month period for written consultation with the public http://www.efsa.eu.int/science/gmo/gmo_consultations/1034_en.html. A similar written consultation on chapter 11 “Environmental Monitoring Plan” (including case specific monitoring) was held prior to the adoption of the EFSA guidance document.

6.3. MON 863 x NK603 maize (application EFSA-GMO-UK-2004-06 under 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 MON 863 x NK603 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. This overall opinion will be published after receipt of the method, validated by the Community reference laboratory, for detection, including sampling, identification of the transformation event and, where applicable, for the detection and identification of the transformation event in the food and/or in foods produced from it.

Discussion

The GMO Panel set up 3 working groups (WG) to examine the MON 863 x NK603 maize application: one WG dealt with the molecular characterisation of the GMO, one dealt with food and feed issues (comparative analysis, toxicology and allergenicity) and the third WG studied the environmental aspects (including post market environmental monitoring) related to the proposed uses of the GM maize.

The assessment is based on the information provided in the application, including additional information from the applicant in reply to questions 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 GMO Panel assessed the MON863 x NK603 maize which is produced by a cross between inbred lines of maize containing MON 863 and NK603 events. The MON 863 and NK603 maize were evaluated previously and NK603 has been authorized. In assessing the MON 863 x NK603 maize, both the single insert lines and the MON 863 x NK603 maize were considered. The Panel concluded that it was acceptable to use data for the single insert lines MON 863 and NK603 in support of the safety assessment of the MON 863 x NK603 maize. However, appropriate data for the hybrid were presented.

The results of the safety assessment do not indicate adverse effects from consumption of MON 863 x NK603 maize and the Panel concludes that there are no concerns over its safety.

In conclusion, the Panel considers that information available for MON 863 x NK603 maize addresses the outstanding questions raised by the Member States and considers that it will not have an adverse effect on human and animal health or the environment in the context of its proposed use.

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/1032/gmo_opinion_ej255_mon863xnk603_en1.pdf

After receipt of all particulars according to Articles 6(5) and 18(5) of Regulation (EC) 1829/2003, the overall opinion will be published at

http://www.efsa.eu.int/science/gmo/gm_ff_applications/more_info/703_en.html.

6.4. MON 863 x MON 810 x NK603 maize (application EFSA-GMO-BE-2004-07 under 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 MON 863 x MON 810 x NK603 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. This overall opinion will be published after receipt of the method, validated by the Community reference laboratory, for detection, including sampling, identification of the transformation event and, where applicable, for the detection and identification of the transformation event in the food and/or in foods produced from it.

Discussion

The GMO Panel set up 3 working groups (WG) to examine the MON 863 x NK603 maize application: one WG dealt with the molecular characterisation of the GMO, one dealt with food and

feed issues (comparative analysis, toxicology and allergenicity) and the third WG studied the environmental aspects (including post market environmental monitoring) related to the proposed uses of the GM maize.

The assessment is based on the information provided in the application, including additional information from the applicant in reply to questions 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 GMO Panel assessed the maize MON 863 x MON 810 x NK603 which is produced by a cross between inbred lines of maize containing MON 863, MON 810 and NK603 events. The MON 863, MON 810 and NK603 maize were evaluated previously and MON 810 and NK603 has been authorized. In assessing the MON 863 x MON 810 x NK603 maize, both the single insert lines and MON 863 x MON 810 x NK603 maize were considered. The Panel concluded that it was acceptable to use data for the single insert lines MON 863, MON 810 and NK603 in support of the safety assessment of the MON 863 x MON 810 x NK603 maize. However, appropriate data for the hybrid were presented.

The results of the safety assessment do not indicate adverse effects from consumption of MON 863 x MON 810 x NK603 maize and the Panel concludes that there are no concerns over its safety.

In conclusion, the Panel considers that the information available for MON 863 x MON 810 x NK603 maize addresses the outstanding questions raised by the Member States and considers that it will not have an adverse effect on human and animal health or the environment in the context of its proposed use.

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/1033/gmo_opinion_ej256_mon863xmon810xnk603_en1.pdf

After receipt of all particulars according to Articles 6(5) and 18(5) of Regulation (EC) 1829/2003, the overall opinion will be published at http://www.efsa.eu.int/science/gmo/gm_ff_applications/more_info/720_en.html.

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

7.1. EFSA-GMO-NL-2005-16: 281-24-236/3006-210-23 Cotton under Regulation 1829/2003

EFSA received, via the Netherlands, a new application (EFSA-GMO-NL-2005-16) within the framework of Regulation (EC) 1829/2003 for a scientific opinion on GM cotton 281-24-236/3006-210-23 for food and feed use. The same transformation event was already submitted under Directive 2001/18/EC (application number C/NL/04/01). The risk assessment of both applications will be combined.

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 are being consulted by EFSA. These comments will be considered during the assessment of the application by the GMO Panel.

7.2. EFSA-GMO-UK-2005-17: 1507 x NK603 maize under Regulation 1829/2003

EFSA received, via the UK, a new application (EFSA-GMO-UK-2005-17) within the framework of Regulation (EC) 1829/2003 for a scientific opinion on GM maize 1507 x NK603 for import and processing, food and feed use, and cultivation.

In accordance with Article 6.3(c) and 19.3(c) of Regulation (EC) 1829/2003, if an application concerns GMOs to be used as seeds or other plant-propagating material, EFSA shall ask a national competent authority within the meaning of Article 4 of Directive 2001/18/EC to carry out the environmental risk assessment. Therefore, EFSA has approached the national competent authorities under Directive 2001/18/EC for expression of interest to carry out the environmental risk assessment of application EFSA-GMO-UK-2005-17.

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.

8. UPDATE ON APPLICATIONS RECEIVED UNDER DIRECTIVE 2001/18/EC

The EFSA secretariat sent a letter to DG Environment regarding the deadline for scientific opinions on GMO applications pending under Directive 2001/18/EC. Facing an increasing number of requests for opinions on GMO applications notified either under Directive 2001/18/EC or under Regulation (EC) No 1829/2003, it is likely that the adoption of some opinions will be delayed. Most of the applications pending under the Directive concern transformation events which have been notified under the Regulation as well. To make best use of resources, 2001/18-applications will be evaluated together with the corresponding ones of the same GMO introduced under the Regulation.

- Question from the Commission regarding GM rice LLRice62 (application C/GB/03/M5/3 under Directive 2001/18/EC)

This item was discussed together with application EFSA-GMO-UK-2004-04 under Regulation (EC) 1829/2003. The EFSA GMO Panel has assessed the scientific data in the dossier in detail to ensure that Member States questions can be dealt with comprehensively. It was for this reason that questions related to the molecular characterization, food and feed and environmental assessment were asked of the applicant. However, in its response to these questions the applicant has not addressed all of the specific points raised. Without these responses the Panel will be unable to complete a risk assessment of the event and the application will be put on hold. The Panel reiterated its questions to the applicant and asked in addition for a full environmental risk assessment.

- Question from the Commission regarding GM oilseed rape MS8, RF3 and MS8 x RF3 (application C/BE/96/01 under Directive 2001/18/EC)

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

- Question from the Commission regarding GM potato EH92-527-1 (application C/SE/96/3501 under Directive 2001/18/EC)

This item was discussed together with application EFSA-GMO-UK-2005-14 under Regulation (EC) 1829/2003. The applications are under evaluation by the three working groups (molecular characterisation, food/feed safety and environmental risk assessment) of the GMO Panel and will be on the agenda of the next working group meetings.

9. UPDATE ON APPLICATIONS RECEIVED UNDER REGULATION (EC) 1829/2003

- 1507 x NK603 maize (applications EFSA-GMO-UK-2004-05 and EFSA-GMO-UK-2005-17)

The Panel has formulated a question to the applicant for further clarification as regards the molecular characterisation of GM maize 1507 x NK603 following the comments received from the Member States.

- LLRice62 (application C/GB/03/M5/3) and potato EH92-527-1 (application C/SE/96/3501)

See item 8.

10. APPOINTMENT OF RAPPORTEURS FOR NEW QUESTIONS

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

11. STAKEHOLDER ISSUES

The Panel was informed about the different requests for public access to applications or certain parts/documents of the applications and about questions raised by interested parties which were answered by the GMO unit.

12. DATES OF FUTURE MEETINGS

Meeting dates were agreed at an earlier plenary meeting.

13. ANY OTHER BUSINESS

The GMO Panel was informed about the Council vote on safeguard clauses and GM maize MON 863

(<http://europa.eu.int/rapid/pressReleasesAction.do?reference=IP/05/793&format=HTML&aged=0&language=EN&guiLanguage=en>).