European Food Safety Authority

MINUTES OF THE 21ST PLENARY MEETING OF THE SCIENTIFIC PANEL ON GENETICALLY MODIFIED ORGANISMS HELD ON 13-14 SEPTEMBER 2005 (ADOPTED ON 12 OCTOBER 2005)

AGENDA

PARTICIPANTS

GMO Panel:
Hans Christer Andersson, Detlef Bartsch[1] Hans-Joerg Buhk[1], Howard Davies, Marc De Loose[1], Mike Gasson, Niels Bohse Hendriksen, John Heritage[2], Sirpa Kärenlampi, Ilona Kryspin-Sorensen, Harry Kuiper (Chair), Marco Nuti, Fergal O'Gara (Vice-Chair), Pere Puigdomenech, George Sakellaris, Joachim Schiemann, Jeremy Sweet (Vice-Chair), and Jan Dick Van Elsas[2].

EFSA:
Anna Christodoulidou (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), Paula Rey Garcia[2] (DG ENV).

APOLOGIES

GMO Panel:
Willem Seinen, Angela Sessitsch and Jean-Michel Wal.

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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 (GM soybean A2704-12[3], GM maize GA21[4]), 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

[1] Not present 13 September 2005
[2] Not present 14 september 2005
[3] GM soybean A2704-12: declarations were made by Hans-Joerg Buhk, Gijs Kleter and Joachim Schiemann.
[4] GM maize GA21: declarations were made by Detlef Bartsch, Hans-Joerg Buhk, Gijs Kleter, Joachim Schiemann and Jeremy Sweet.

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. Regarding the maize GA21 application, one expert[5] declared that its institute by which he was employed conducted an agronomic study as well as a biosafety study on GA21 maize. This expert will therefore abstain from voting on this opinion.

4. ADOPTION OF THE MINUTES OF THE 20TH PLENARY MEETING HELD ON 5-6 JULY 2005

The minutes of the 20th plenary meeting (5-6 July 2005) were adopted as proposed. The minutes of this meeting are published at:

http://www.efsa.eu.int/science/gmo/gmo_meetings/1020/gmo_minutes_20th_plenmeet1.pdf

5. FEEDBACK FROM EFSA

EFSA has initiated the process for the designation of competent organisations in accordance with Article 36 of Regulation 178/2002. A letter of Geoffrey Podger, the Executive Director of EFSA has been sent to the Permanent Representations of the Member States to the European Union, as well as a questionnaire to be completed by each organisation considering applying for the status as competent organisation:
http://www.efsa.eu.int/about_efsa/cooperation/cooperation_under_art_36/1065_en.html.

6. FEEDBACK FROM THE COMMISSION

The Chairman of the GMO Panel has been requested by the European Commission to provide scientific advice on GMO related matters at the fifth session of the Codex Alimentarius ad hoc intergovernmental Task Force on foods derived from biotechnology (Chiba, Japan, 19 - 23 September 2005).

7. DISCUSSION AND POSSIBLE ADOPTION OF OPINIONS ON:

7.1. Question from the Commission on the safety and efficacy of the enzyme preparation Phytase SP 1002 for use as feed additive for piglets, pigs for fattening, sows, chickens for fattening, turkeys and laying hens (co-opinion of FEEDAP and GMO Panels)

EFSA received a request from the Commission to deliver an opinion on the safety of the enzyme product Phytase SP 1002 for the target animals, the user, the consumer and the environment and the efficacy when used under the proposed conditions.

The GMO Panel has been asked to perform the assessment of the genetic modification aspects of the micro-organism used for the production of the feed enzyme. The risk assessment should be performed following the scientific principles and approach described in the draft guidance

[5] Jeremy Sweet.

document on GMMs, currently under public consultation (http://www.efsa.eu.int/science/gmo/gmo_consultations/1035/gmo_consultation_guide_gmm2_en1.pdf). The FEEDAP Panel will assess all other parts of the application, and a joint, final opinion will be adopted by both the FEEDAP Panel and the GMO Panel.

As regards the genetic modification aspects, the GMO Panel formulated questions to the applicant for further molecular data on the product.

7.2. Question from the Commission on the safety and efficacy of the enzymatic preparation Phyzyme XP for use as feed additive for chickens for fattening (co-opinion of FEEDAP and GMO Panels)

EFSA received a request from the Commission to deliver an opinion on the efficacy and the safety of the enzymatic preparation Phyzyme XP for the consumer, the user and the workers and for the target animal category.

In analogy to the Phytase SP 1002 application (see 7.1), the GMO Panel has performed the assessment of the genetic modification aspects of the Phyzyme XP. The GMO Panel identified some issues as regards the molecular data in the dossier to be further clarified by the applicant.

7.3. Question from the Commission on MS8, RF3 and MS8 x RF3 oilseed rape (application C/BE/96/01 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 oilseed rape MS8, RF3 and MS8x RF3 for import, processing and cultivation 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.

However, this request, including cultivation, was in contradiction with the supporting documents provided by the Commission (*e.g.* support by Competent Authorities to exclude cultivation). As the risk assessment carried out by the lead Competent Authority was not clear with respect to cultivation, the assessment of the data related to cultivation by the other Member States was incomplete and not further supported by the applicant.

Article 29(4) of Regulation (EC) 178/2002 (EC, 2002a) states that, where the request to EFSA is not clear, the Authority may either refuse or propose amendments to a request for an opinion in consultation with the Institution or Member States that made the request. Therefore, pending further clarifications about the limitation of scope of the application, EFSA suggested an amendment of the terms of reference and the GMO Panel did not to assess the data provided by the applicant related to the cultivation of oilseed rape Ms8, Rf3 and Ms8 x Rf3.

Discussion

The GMO Panel set up 3 working groups (WG) to examine the MS8, RF3 and MS8 x RF3 oilseed rape 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 oilseed rape.

The assessment is based on the information provided in the application, including additional information from the applicant in reply to questions from Member 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 GMO Panel considered all the information made available by the applicant as sufficient to assess the safety of Ms8, Rf3, Ms8 x Rf3 oilseed rape with reference to the intended uses (import and processing of Ms8 x Rf3 oilseed rape for feed and industrial purposes) and to address all the specific questions raised by the Member States related to risk assessment, except the ones with respect to cultivation.

The GMO Panel has considered information provided on (1) the molecular inserts within the transgenic events Ms8 and Rf3 and the resulting hybrid, (2) the compositional analysis of Ms8 x Rf3 oilseed rape and its non transgenic comparator, (3) the safety of the proteins expressed and (4) the potential for risks associated with any changes to the toxicological, allergenic or nutritional properties of Ms8 x Rf3 oilseed rape.

From all evidences provided, the GMO Panel is of the opinion that Ms8, Rf3, Ms8 x Rf3 oilseed rape is as safe as conventional oilseed rape for humans and animals and, in the context of the proposed uses, for the environment.

The GMO Panel considers the environmental risk assessment and monitoring plan for import acceptable in the light of the intended uses. The GMO Panel advises that appropriate management systems should be in place to minimize accidental loss and spillage of transgenic oilseed rape during transportation, storage, handling in the environment and processing into derived products.

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/1178/gmo_op_ej281_ms8xrf3_1.pdf

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

8.1. Application EFSA-GMO-NL-2005-18: A2704-12 Soybean under Regulation 1829/2003

EFSA received, via the Netherlands, a new application (EFSA-GMO-NL-2005-18) within the framework of Regulation (EC) 1829/2003 for a scientific opinion on GM soybean A2704-12 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/1062/summary_efsa_gmo_nl_2005_181.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 are being consulted by EFSA. These comments will be considered during the assessment of the application by the GMO Panel.

8.2. Application EFSA-GMO-UK-2005-19: GA21 maize under Regulation 1829/2003

EFSA received, via the UK, a new application (EFSA-GMO-UK-2005-19) within the framework of Regulation (EC) 1829/2003 for a scientific opinion on GM maize GA21 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/1125/summary_efsa_gmo_uk_2005_191.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 are being consulted by EFSA. 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. INTERACTION WITH MEMBER STATES AS REGARDS THE ENVIRONMENTAL RISK ASSESSMENT OF GMOS FOR CULTIVATION SUBMITTED UNDER REGULATION 1829/2003

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 as this application is intended for cultivation of 1507 x NK603 maize.

EFSA is awaiting the answer of interested competent authorities to perform the environmental risk assessment of this application.

The Panel has been asked to comment on a draft note submitted by the secretariat describing the legal base and the procedure as regards the interaction with Member States for the environmental risk assessment of applications.

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

- 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 Panel has formulated questions to the applicant for further clarification as regards the molecular characterisation and food/feed safety of GM potato EH92-527-1.

- 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 had a discussion on the scope of the application and concluded that the scope only covers derived food and feed products but not consisting or containing GMOs.

11. APPOINTMENT OF RAPPORTEURS FOR NEW QUESTIONS

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

12. 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.

13. DATES OF FUTURE MEETINGS

New dates for working group meetings have been scheduled for the first half of 2006.

14. ANY OTHER BUSINESS

The Panel was informed about a letter of the Dutch competent authority (COGEM, Commissie Genetische Modificatie) concerning their assessment of an EFSA opinion on the cultivation of Bt11 maize. The advice of COGEM as regards the safety of Bt11 maize is in line with the opinion of the GMO Panel. COGEM raised some specific remarks with respect to the environmental risk assessment which will be addressed at a later plenary meeting.

The Panel proposed to organise a meeting of representatives of the GMO and PPR Panels and the Commission to discuss risk assessment of GM crops and microorganisms with specific pesticide interactions. Currently GMOs and pesticides are subject to different EC regulations and Directives and EFSA is requested to give opinions on their safety for human health and the environment according to the remit of these regulations. The GMO and PPR panels are concerned that GMOs that interact with pesticides by either producing biocides, tolerating pesticides or having specific associations with pesticides, have full evaluations of all aspects of their safety. They are particularly concerned that certain risks are not missed because they fall between the different regulations and incorrect assumptions are made about the remit of the different panels. In addition there is a concern that different criteria may be used to evaluate safety or that there is duplication in the work of the two panels.