European Food Safety Authority

MINUTES OF THE 19TH PLENARY MEETING OF THE SCIENTIFIC PANEL ON GENETICALLY MODIFIED ORGANISMS HELD ON 8-9 JUNE 2005 (ADOPTED ON 5 JULY 2005)

AGENDA

PARTICIPANTS

GMO Panel:
Hans Christer Andersson, Detlef Bartsch[1] Hans-Joerg Buhk, Howard Davies, Marc De Loose, Niels Bohse Hendriksen[2], John Heritage, Sirpa Kärenlampi, Ilona Kryspin-Sorensen, Harry Kuiper (Chair), Marco Nuti, Pere Puigdomenech, Joachim Schiemann[2], Willem Seinen, Jeremy Sweet (Vice-Chair)[2], Jan Dick Van Elsas[2] and Jean-Michel Wal[2].

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) [1], Sebastien Goux (DG SANCO D4)[1], Aurelie Andre (DG ENV B)[2].

APOLOGIES

GMO Panel:
Mike Gasson, Fergal O'Gara, George Sakellaris, Angela Sessitsch.

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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 cottonseed 281-24-236/3006-210-23[3], 1507x59122 maize[4]), some members indicated that they had been to some extent involved in the safety assessment

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[1] Not present on 9 June 2005 in the afternoon session.

[2] Not present on 9 June 2005.

[3] Cottonseed 281-24-236/3006-210-23: declarations were made by Detlef Bartsch, Hans-Joerg Buhk, Gijs Kleter, Harry
Kuiper and Joachim Schiemann.

[4] 1507x59122 maize: Detlef Bartsch, Hans-Joerg Buhk, and Joachim Schiemann.

process of this application at national level and provided a written declaration. It was decided from these 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 18TH PLENARY MEETING HELD ON 2-4 MARCH 2005

The minutes of the 18th plenary meeting (20-21 April 2005) were adopted as proposed. The minutes of this meeting are published at:

http://www.efsa.eu.int/science/gmo/gmo_meetings/893/gmo_minutes_18th_plenmeet1.pdf

5. FEEDBACK FROM AND TO THE SCIENTIFIC COMMITTEE/EFSA

The Panel discussed the need for an improved internal working procedure as the Panel is facing increasing workload from the number of dossiers and important self-tasking exercises it needs to undertake and from the high number of scheduled working group meetings, including travelling time. The latter will even be increased following the relocation of EFSA to Parma.

The Panel also agreed on possible solutions for the improved internal operation of the GMO Panel concerning allocation of tasks, and commitment to the responsibilities and deadlines.

6. DISCUSSION AND POSSIBLE ADOPTION OF OPINIONS ON:

6.1. MON 863 x MON 810 maize (application EFSA-GMO-DE-2004-03 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 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.

The Panel was not requested to give an opinion on information required under Annex II to the Cartagena Protocol. The Panel did also not consider proposals for labelling and methods of detection (including sampling and the identification of the specific transformation event in the food and/or foods produced from it) which are matters related to risk management.

Discussion and adoption

See item 6.2.

6.2. MON 863 x MON 810 maize (application C/DE/02/9 under 2001/18/EC)

Introduction

The GMO Panel was asked to provide a scientific opinion as to whether there is any scientific reason to believe that the placing on the market of the genetically modified maize MON 863 x MON 810, for import and processing, is likely to cause any adverse effects on human health and the environment within the scope of Directive 2001/18/EC.

Discussion

Item 6.1 was discussed along with item 6.2. 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 GMO Panel set up 3 working groups (WG) to examine simultaneously both applications (C/DE/02/9 and EFSA-GMO-DE-2004-03): 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 two applications, including additional information from the applicant in reply to questions from Members States (MS) and from EFSA. On 2 April 2004 the GMO Panel already issued two opinions concluding on the safety of MON 863 maize. However, no agreement could be reached on the safety evaluation of the MON 863 x MON 810 maize. To resolve this issue, EFSA decided to request a 90-day study from the applicant, in order to allow the Panel to finalise its evaluation.

The 90-day rat study was provided by the applicant and the Panel focussed its assessment in particular on this new study, and took also into account the comments from MS consulted by EFSA in accordance with Articles 6(4) and 18(4) of Regulation (EC) No 1829/2003 for the EFSA-GMO-DE-2004-03 application, including the national Competent Authorities within the meaning of Directive 2001/18/EC.

EFSA had requested the 90-day study following the fact that the Panel at that time could not reach agreement on the safety evaluation of MON 863 x MON 810 maize. The Panel noted that the 90-day study did not reveal safety concerns about this GM maize. However, the need for a 90-day study has to be decided on a case-by-case basis. The Panel referred to the self task on animal feeding trials (see item 7.3). The mandate of this self task is to look at the limitations and potentialities of animal feeding studies for the safety evaluation of whole foods/feed.

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 MON 863 x MON 810 maize which is produced by a cross between inbred lines of maize containing MON 863 and MON 810 events. The MON 863 and MON 810 maize were evaluated previously and MON 810 has been authorized. In assessing MON 863 x

MON 810 maize, both the single insert lines and MON 863 x MON 810 maize were considered. The Panel concluded that it was acceptable to use data for the single insert lines MON 863 and MON 810 in support of the safety assessment of MON 863 x MON 810 maize.

The results of 90-day sub-chronic rodent study do not indicate adverse effects from consumption of maize MON 863 x MON 810 maize and the Panel concludes that there are no resultant concerns over its safety. The Panel considers that the data from the 90-day rat feeding study with grain from MON 863 x MON 810 maize are sufficient to conclude that there is no reason to assume that MON 863 x MON 810 maize is different from the conventional maize regarding its safety.

In conclusion, the Panel considers that the information available for MON 863 x MON 810 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 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/1031/gmo_opinion_ej252_mon863x810_2_en1.pdf
http://www.efsa.eu.int/science/gmo/gmo_opinions/1030/gmo_opinion_ej251_mon863x810_en1.pdf

6.3. Safeguard clause Hungary

Introduction

EFSA received from the Commission a request to provide a scientific opinion as to whether, in accordance with Article 23 of Directive 2001/18/EC, the statements and documents submitted by the Hungarian authorities comprise new or additional information affecting the environmental risk assessment or re-assessment of existing information on the basis of new or additional scientific knowledge such that detailed grounds exist to consider that the authorized MON 810 maize (reference C/F/95/12-02), for the uses laid down in the corresponding consents, constitute a risk to human health or the environment.
EFSA is not requested to give an opinion on political, economic and legal arguments put forward by Hungary in the context of the application of legislation or requests for further legislative/implementing measures.

Discussion

The draft opinion on the Hungarian safeguard clause was presented to the Panel members during the Plenary meeting. Although all members agreed on the overall content of the opinion, some editorial changes and suggestions for clarification were discussed.

As a main conclusion the opinion states that:

The Scientific Panel on Genetically Modified Organisms, having considered the scientific information submitted by Hungary, is of the opinion that

- there is no new data that would invalidate the provisions for the environmental risk assessment established under Directive 90/220/EEC or Directive 2001/18/EC.

- there is no specific scientific evidence, in terms of risk to human health and the environment, that would justify a prohibition of the genetically modified crops authorised under Directive 90/220/EEC or Directive 2001/18/EC in Hungary.

In conclusion, the Panel finds that the scientific evidence currently available does not sustain the arguments provided by Hungary. The GMO Panel strongly recommends that in order to facilitate a thorough assessment of the identified risk, Member States should support any claims to invoke the safeguard clause by supplying an appropriate risk assessment accompanied by the supporting new scientific data of a quality which can be subjected to detailed scientific scrutiny.

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/1046/gmo_opinion_ej228_safeguards_en1.pdf

7. PROGRESS REPORTS ON:

7.1. Question from the Commission regarding guidance for GM food and feed applications under Regulation (EC) 1829/2003: Guidance on GM food/feed containing GMM

The outcome of the working group meeting held on 19 May 2005 was presented to the Panel. It was decided at that meeting that biofertilisation and bioremediation products should not be covered in the guidance document, but considering the importance of these issues, may be addressed at a later date. The document has also been revised by the working group taking into account the suggestions made at the last Plenary meeting. Groups of GMM food/feed derived products have been re-defined in the document and a paragraph on post-market environmental monitoring has been included.

The revised guidance document was sent to the Panel members for comments. A final version will be presented at the next plenary meeting for adoption.

7.2. Self tasking activity post market environmental monitoring

The outcome of the last working group meeting on post market environmental monitoring (PMEM) held on 31 May 2005 was presented to the Panel. The revised Chapter 11.4 (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 will be submitted to the Panel for final adoption at the next plenary meeting.

The working group members have also decided at their last meeting to draft a scientific opinion which reflects the outcomes of the discussions in the working group and of the different workshops[5] held with stakeholders and which will address more general recommendations on PMEM.

7.3. Self tasking activity on animal feeding trials

[5] http://www.efsa.eu.int/science/gmo/gmo_consultations/732_en.html

A follow-up of the third working group meeting on the use of animal feeding trials for whole GMO food/feed held on 3 June 2005 was presented to the Panel. The members discussed the revised outline of issues to be addressed by the working group and some additional contributions to these tasks from working group members. The outline will encompass a two-steps process, the first part consisting of the different existing tests (in vitro/in vivo) and their performances regarding the safety testing of whole GMO food/feed, the second part reporting on how these tests can be used for regulatory purposes.

7.4. Applications regarding feed additives produced by GMMs

A new working group has been created for the assessment of the genetic modification part of applications concerning feed additives produced by GMMs, for which the main part of the assessment is done by the EFSA FEEDAP Panel. A first meeting has been scheduled to assess two applications (Phyzyme XP and Phytase SP 1002) within the framework of Directive 70/524/EEC and Regulation (EC) 1831/2003.

8. SELF TASK ON THE "ASSESSMENT OF GM PLANTS USED AS PRODUCTION PLATFORM FOR NON-FOOD PRODUCTS"

The draft mandate for the self task on the assessment of GM plants used as production platform for non-food products was adopted by the Panel. As the scope of the self task has been broadened, it was suggested to extend the list of external experts with experts in the field of non-food products other than pharmaceuticals.

A background document, the mandate as well as an indication of the timeframe for this activity will be submitted to the EFSA Deputy Executive Director and Director of Science for approval.

9. NEW REQUESTS FROM COMMISSION: DISCUSSION AND ADOPTION OF MANDATES

9.1. Question from Commission regarding GM cottonseed 281-24-236/3006-210-23 (C/NL/04/01)

EFSA received from the Commission a request for a scientific opinion on GM cottonseed 281-24-236/3006-210-23 from Agrigenetics/Mycogen Seeds c/o DOW Agrosciences introduced under Directive 2001/18/EC (EFSA-Q-2005-072) for import and industrial processing (C/NL/04/01).

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

- LLRice62: Question from the Commission regarding 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 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.

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

The Panel has formulated some questions to the applicant for further clarification as regards the molecular characterisation and the food/feed safety of GM oilseed rape MS8, RF3 and MS8 x RF3.

11. UPDATE ON APPLICATIONS RECEIVED UNDER REGULATION 1829/2003

Since the last Plenary meeting, EFSA received, via the Netherlands and the United Kingdom, two additional applications within the framework of Regulation (EC) 1829/2003, bringing the total number of applications received by EFSA under this Regulation to fifteen.

New applications (under completeness check):
- Potato EH92-527-1 (EFSA-GMO-UK-2005-14)
- 1507x59122 maize (EFSA-GMO-NL -2005-15)

The summary of the applications can be found on the following website: http://www.efsa.eu.int/science/gmo/gm_ff_applications/catindex_en.html.

12. APPOINTMENT OF RAPPORTEURS FOR NEW QUESTIONS

Rapporteurs have been appointed for the new applications mentioned under items 9&11.

13. ACCESS TO DOCUMENTS

The Panel was informed about the different requests for public access to applications or certain parts/documents of the applications (see the minutes of the 18th Plenary meeting of the GMO Panel on the procedure to be followed under Regulation (EC) 1049/2001 for public access and regarding the confidentiality status).

14. STAKEHOLDER ISSUES

In the media some confusing information appeared about a "secret 1139 page report" study from Monsanto and the fact that EFSA only received partial information of this study. Following these press releases, EFSA issued a statement[6] clarifying the status of the risk assessment of MON 863 maize and the hybrid MON 863 x MON 810. EFSA had received the full "1139 page report" that concerned a 13-week study conducted in rats with MON 863 maize which had been reviewed by the GMO Panel in carrying out its risk assessment, and which has also been confirmed in a later statement of the GMO Panel[7]. On 2 April 2004, the Panel has adopted two opinions on MON 863 maize under different regulatory frameworks[8]. With regard to the hybrid MON 863 x MON 810, it is stated in these opinions that the Panel could not reach a conclusion with regard to the safety evaluation of the hybrid. For this reason, EFSA requested a 90-day animal feeding study with MON

[6] http://www.efsa.eu.int/press_room/press_statements/929/ps_gmo_mon863_v3_en1.pdf
[7] http://www.efsa.eu.int/science/gmo/statements/666/sr_gmo01_statement_study_mon863_en1.pdf
[8] http://www.efsa.eu.int/science/gmo/gmo_opinions/381/opinion_gmo_06_en1.pdf;
http://www.efsa.eu.int/science/gmo/gmo_opinions/383/opinion_gmo_07_en1.pdf

863 x MON 810 maize (see items 6.1&6.2 on the further follow-up and on the evaluation of this study by the GMO Panel).

15. DATES OF FUTURE MEETINGS

Some dates were set for Plenary meetings in 2006 in Parma:

- 24-25 January 2006
- 28-29 March 2006
- 16-17 May 2006

16. ANY OTHER BUSINESS

EFSA had been informed by the Commission on a comment from Norway about the possible allergenic risk of the insect resistance protein in 1507 maize. The Panel was aware of the publications made available by Norway and concluded that there is no new information that would change the safety evaluation of 1507 maize earlier performed by the Panel.

The Panel was informed about the request from the Italian delegation to the Council that EFSA should commission its own laboratory work in the area of GMOs to verify applicants' data by means of testing. The Panel notes that studies included in the application have to meet appropriate quality assurance criteria (e.g. GMP, GLP, ISO) as done for all applications to place products on the market (e.g. food and feed additives, pesticides…). Experimental studies are not within the remit of EFSA.