



**MINUTES OF THE 16TH PLENARY MEETING OF THE
SCIENTIFIC PANEL ON GENETICALLY MODIFIED ORGANISMS
HELD ON 18-19 JANUARY 2005
(ADOPTED ON 2 MARCH 2005)**

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PARTICIPANTS

GMO Panel:

Hans Christer Andersson, Detlef Bartsch¹, Howard Davies, Marc De Loose, Michael Gasson¹, John Heritage, Sirpa Kärenlampi, Ilona Kryspin-Sorensen, Harry Kuiper (Chair), Marco Nuti, Fergal O’Gara¹ (Vice-Chair), Pere Puigdomenech Rosell¹, George Sakellaris, Joachim Schiemann², Angela Sessitsch, Jeremy Sweet (Vice-Chair) and Jean-Michel Wal

Ad Hoc experts²:

Gijs Kleter (RIKILT, Wageningen)

EFSA:

Anna Christodoulidou (scientific officer), Karine Lheureux (scientific officer), Luisa Mannu (scientific officer), Suzy Renckens (scientific co-ordinator GMO Panel), Markus Röver (scientific officer), Ellen Van Haver (assistant scientific co-ordinator GMO Panel)

European Commission:

Dorothee André-Schoboboda (DG SANCO E1), Dyanne Bennink (DG RTD E2), Katja Neubauer (DG SANCO D3), Michael Walsh (DG SANCO D5 – Interface Unit)

APOLOGIES

GMO Panel:

Hans-Joerg Buhk, Niels Hendriksen, Willem Seinen and Jan Dirk 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 GM maize 1507 and GM maize Bt11 applications were noted during the 10th Plenary meeting:

http://www.efsa.eu.int/science/gmo/gmo_meetings/388/minutes_gmo_10_en1.pdf

¹ Only present on 19 January

² Only present on 18 January

As regards GM LLRice62, possible interests were declared at the 15th Plenary meeting:

http://www.efsa.eu.int/science/gmo/gmo_meetings/729/minutes_plenary15final1.pdf

As regards H7-1 Roundup Ready sugar beet³, MON531 x MON1445 cotton, MON15985 and MON15985 x MON1445 cotton and MIR604 maize⁴, some members indicated that they had been to some extent involved in the safety assessment 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 15TH PLENARY MEETING HELD ON 8-9 DECEMBER 2004

The minutes of the 15th plenary meeting (8-9 December 2004) were adopted as proposed. The minutes of this meeting are published at:

http://www.efsa.eu.int/science/gmo/gmo_meetings/729/minutes_plenary15final1.pdf

5. DISCUSSION AND POSSIBLE ADOPTION OF OPINION ON:

5.1. Question from the Commission regarding GM maize 1507 (application C/ES/01/01 under 2001/18/EC)

Introduction

The GMO Panel was tasked to provide a scientific opinion as to whether there is any scientific reason to believe that placing 1507 maize on the market for import, feed and industrial processing, and cultivation is likely to cause any adverse effects on human health and the environment within the scope of Directive 2001/18/EC.

Discussion

Item 5.1 was discussed along with item 5.2. 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, except for the cultivation aspects. 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/ES/01/01 and EFSA-GMO-NL-2004-02): 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.

³ H7-1 Roundup Ready sugar beet: Declarations were made by Detlef Bartsch, Hans-Joerg Buhk, Gijs Kleter, Harry Kuiper and Joachim Schiemann.

⁴ MON531 x MON1445 cotton, MON15985 and MON15985 x MON1445 cotton and MIR604 maize: Declarations were made by Detlef Bartsch, Hans-Joerg Buhk and Joachim Schiemann.

The assessment is based on the information provided in the two applications, including additional information from the applicant in reply to questions from Member States (MS) and from EFSA, as well as on the application C/NL/00/10 submitted under 2001/18/EC and for which the GMO Panel already delivered an opinion⁵. The Panel focused in its evaluation in particular on the issues that were raised by MS during their initial assessment of the C/ES/01/01 application introduced under 2001/18/EC. The Panel took also into account the comments from nominated risk assessment bodies of the MS consulted by EFSA for the EFSA-GMO-NL-2004-02 application, including the national Competent Authorities within the meaning of Directive 2001/18/EC following the requirements of Article 6(4) of Regulation 1829/2003.

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:

Maize line 1507 has been developed for protection against lepidopteran pests by expressing the Cry1F Protein and for tolerance to glufosinate by the introduction of a *pat* gene. The GMO Panel has assessed information provided on molecular inserts within the transgenic event, on the safety of the proteins expressed and on the potential for risks associated with any changes to the nutritional, toxicological and allergenic properties of 1507 maize. Analysis of the chemical composition of the maize and field trial data were also used to assess the potential for changes to safety, nutritional as well as agronomic parameters. No data have emerged to indicate that maize line 1507 is any less safe than its non-GM comparators.

The Panel considers that 1507 maize will have similar impacts as other comparable non-GM maize cultivars on the environment. The only adverse effect identified was the possibility that resistance to *Bt* toxin might evolve in corn borers exposed to 1507 maize following cultivation for some years. The Panel accepts the monitoring plan developed by the applicant to monitor specifically for resistance in corn borers and recommends that cultivation should be accompanied by appropriate risk management strategies to minimise exposure of both target and non-target insects to *Bt* toxins. In addition, the Panel accepts in principle the general surveillance plan submitted by the applicant.

The EFSA GMO Panel is therefore of the opinion that there is no evidence to indicate that placing of maize line 1507 and derived products on the market is likely to cause adverse effects on human or animal health or the environment in the context of its proposed use.

The authorisation of the complementary herbicide is not within the remits of this opinion and is covered by other legal frameworks of the EU and Member States.

With regard to the EFSA-GMO-NL-2004-02 application (submitted under Regulation 1829/2003), the Panel is of the opinion that, based on the outcome of the risk assessment, no specific conditions or restrictions should be imposed on the placing of 1507 maize on the market for food use. No specific conditions or restrictions for food use and handling, including post-market monitoring requirements regarding the use of 1507 maize for human consumption, are regarded as necessary.

⁵ Opinion of the Scientific Panel on Genetically Modified Organisms on a request from the Commission related to the Notification (Reference C/NL/00/10) for the placing on the market of insect-tolerant genetically modified maize 1507, for import and processing, under Part C of Directive 2001/18/EC from Pioneer Hi-Bred International/Mycogen Seeds, The EFSA Journal (2004) 124, 1-18.
http://www.efsa.eu.int/science/gmo/gmo_opinions/663/finalopinion1507maize_import2.pdf

Furthermore, there is no need for specific conditions for the protection of particular ecosystems/environment and/or geographical areas.

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/827/op_gm08_ej181_1507_opinion_doc1_2en1.pdf
http://www.efsa.eu.int/science/gmo/gmo_opinions/826/gmopanelriskassessment1.pdf

5.2. EFSA-GMO-NL-2004-02 GM maize 1507 (former 258/97 application)

Introduction

As regards the application submitted under Regulation 1829/2003, EFSA has to provide an opinion in accordance with Article 6 of Regulation 1829/2003. Application EFSA-GMO-NL-2004-02 covers foods consisting of or derived from genetically modified maize 1507. The feed uses of maize 1507 and the aspects of cultivation, import and processing are covered by other applications⁶.

The opinion of the GMO Panel corresponds to the safety assessment report as referred to in Article 6(6) of Regulation (EC) No 1829/2003 and will be part of the overall EFSA opinion as required by Article 6(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 which are matters related to risk management. The latter would include information on sampling and the identification of the specific transformation event in the food and/or foods produced from it.

Discussion and adoption

See item 5.1.

6. PRESENTATION BY DG RTD ON 7TH FRAMEWORK PROGRAMME

The representative of the Research Directorate General of the European Commission presented the current developments and outlook on European science discussion. The current EU research policy objectives were summarised and the Panel was updated about the outcomes, ongoing activities and outlook of the Framework Programmes. The Panel was invited to provide ideas, suggestions for prioritising the needs for further research in the field of biotechnology.

7. PROGRESS REPORTS ON:

⁶ Notifications C/ES/01/01 and C/NL/00/10 submitted under Directive 2001/18/EC.

7.1. Question from the Commission regarding GM maize Bt11 (application C/FR/96/05/10 under 2001/18/EC)

Additional information was received from the applicant with regard to the post-market environmental monitoring of Bt11 maize. The Panel is however awaiting some further clarification from the applicant.

7.2. Question from the Commission regarding LLRice62 (application C/GB/03/M5/3 under 2001/18)

This item was discussed together with item 8.4. Both applications (C/GB/03/M5/3, under 2001/18 and EFSA-GMO-UK-2004-04, under 1829/2003) will be discussed at the next working group meetings (Molecular Characterisation, Food/Feed Safety and Environmental Risk Assessment).

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

A follow-up of the working group meeting of the GMM guidance document held on 11 January 2005 was presented to the Panel. The Panel discussed whether biofertilisation and bioremediation products should fall within the scope of the GMM guidance document. The Panel proposed to involve other EFSA Panels as well to deal with these products.

A revised version of the current draft guidance document on food/feed derived from GMM will be circulated, for comments and revisions, before the next working group meeting.

7.4. Self tasking activity Post market environmental monitoring

Based on its mandate, the working group on post market environmental monitoring (PMEM) initiated a series of consultation workshops with different stakeholders to establish a rationale and general framework for general surveillance as a component of post market environmental monitoring. A follow-up was given of the second stakeholder consultation with environmental organisations, held on 10 December 2004. The minutes will be published on the EFSA-website. A third consultation with experts from the Member States, as members of the Working Group on Monitoring of the Competent Authorities within the framework of Directive 2001/18/EC, will be held on 20 January 2005.

8. UPDATE ON APPLICATIONS RECEIVED UNDER REGULATION 1829/2003

Since last Plenary meeting, EFSA received, via the UK, three additional new applications within the framework of Regulation (EC) 1829/2003, bringing the total number of applications received by EFSA under this Regulation to eleven.

New applications (under completeness check):

EFSA-GMO-UK-2005-09: GM Cotton MON531 x MON1445

EFSA-GMO-UK-2005-10: GM Cotton MON15985 and MON15985 x MON1445 Cotton

EFSA-GMO-UK-2005-11: GM Maize MIR604

With regard to applications EFSA-GMO-NL-2004-03/04/06/07 (GM maize MON863xMON810, GM rice LLRICE62, GM maize MON863xNK603 and MON863xMON810xNK603), 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 applications by the GMO Panel.

9. APPOINTMENT OF RAPPORTEURS FOR NEW QUESTIONS

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

10. STAKEHOLDER ISSUES

The Chair informed the Panel of the letter he received from Greenpeace regarding the possible impact of Bt pollen from Bt11 and MON810 on the survival of larvae of the monarch butterfly. The Panel considered this information and a reply by the Chair was sent to Greenpeace indicating that risk assessments and research in Europe currently indicate no adverse effects on non-target Lepidoptera and that there is no need to revise risk assessments.

The Panel received a copy of the response by the Chair of the Management Board of EFSA to the letter sent by Friends of the Earth regarding their report “Throwing caution in the wind, A review of the European Food Safety Authority and its work on genetically modified foods and crops”. The response of the Chair of the Management Board can be found on the EFSA-website: http://www.efsa.eu.int/mboard/correspondence/786_en.html.

11. FEEDBACK FROM AND TO THE SCIENTIFIC COMMITTEE

The Chair gave an overview of the outcome of the 10th Plenary meeting of the EFSA Scientific Committee held on 15-16 December 2004. The minutes of this meeting are published at:

http://www.efsa.eu.int/science/sc_committee/sc_meetings/738/minutes10thplenarysc124final1.pdf.

12. DATES OF FUTURE MEETINGS

There were no new dates for future meetings.

13. ANY OTHER BUSINESS

The Panel had a discussion on a proposal for a new self tasking activity on the production of plant made pharmaceuticals in genetically modified crops. The idea for this self tasking activity was already launched at the 3rd GMO Panel Plenary meeting (http://www.efsa.eu.int/science/gmo/gmo_meetings/170/minutes_gmo_03_adopted_en1.pdf), but was at that time put on a hold. The activity is aimed at assessing the use of the GM plants and the environmental aspects of the release of such plants. The Panel will draft a mandate for a self tasking activity. The Panel was also informed about the EU research project Pharma-Planta to produce pharmaceuticals in genetically modified plants (<http://www.pharma-planta.org/>) and the research project on “Molecular Farming” commissioned by the Office of Technology Assessment at the German Parliament, demonstrating the importance of this topic.

The importance of expanding the reserve pool of *ad hoc* experts was acknowledged by the Panel in order to be able to address the increasing amount of requests for assessing applications.
