

**MINUTES OF THE 41ST PLENARY MEETING OF THE
SCIENTIFIC PANEL ON GENETICALLY MODIFIED ORGANISMS
HELD ON 16-17 APRIL 2008 IN PARMA, ITALY
(ADOPTED ON 21 MAY 2008)**

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PARTICIPANTS

GMO Panel:

Hans Christer Andersson, Salvatore Arpaia, Detlef Bartsch, Josep Casacuberta, Howard Davies, Lieve Herman, Sirpa Kärenlampi, Jozsef Kiss, Gijs Kleter, Ilona Kryspin-Sorensen, Harry Kuiper (Chair), Nickolas Panopoulos, Joe Perry, Annette Pöting, Joachim Schiemann, Willem Seinen and Jeremy Sweet.

EFSA:

GMO Unit: Per Bergman, Elisa Bianco, Anna Christodoulidou, Yann Devos, Zoltan Diveki, Antonio Fernandez Dumon, Ana Gomes, Karine Lheureux, Sylvie Mestdagh, Claudia Paoletti, and Reinhilde Schoonjans.

European Commission:

Sebastien Goux (DG SANCO)¹ and Yannis Karamitsios ²(DG ENV).

*Spanish Competent Authority*³

Gema Perez Farinos from Consejo Superior de Investigaciones Científicas (CSIC), Cristina Chueca Castedo from Instituto Nacional de Investigaciones Agrarias (INIA), Ana Fresno Ruiz and Lucía Roda Ghisleri from Ministerio de Medio Ambiente.

APOLOGIES

GMO Panel:

Niels Bohse Hendriksen, Marc De Loose, Ingolf Nes, and Jean-Michel Wal.

1. WELCOME AND APOLOGIES FOR ABSENCE

The Chair opened the meeting and welcomed all. Apologies for absence were received from some Panel members as mentioned above.

One of the Panel members, Prof. Marc De Loose, resigned from the Panel because the workload of his daily activities was no longer compatible with that of the GMO Panel. The Panel expressed its thanks and appreciation for his contribution. A new GMO Panel member will be selected from the reserve list.

The Chair of the Panel welcomed the new Head of the GMO Unit, Dr Per Bergman. Dr Bergman introduced himself to the Panel through a short presentation of his scientific background in Biology/Molecular genetics and his previous risk management activity for the Swedish Ministry of Agriculture. A tour de table was held to introduce all the Panel members.

2. ADOPTION OF THE AGENDA

The agenda was adopted as proposed.

¹ Only present from point 6 onwards

² Only present on 16 April from point 1 to point 8

³ Only present for Agenda item 6

3. DECLARATION OF INTERESTS

Panel members were invited to declare possible interests on topics included on the agenda. No declarations of interest were declared.

4. ADOPTION OF THE MINUTES OF THE 40TH PLENARY MEETING HELD ON 12-13 MARCH 2008

The minutes of the 40th Plenary meeting (12-13 March 2008) were adopted as proposed and will be published at:

http://www.efsa.europa.eu/EFSA/efsa_locale-1178620753812_1178692526369.htm

5. DISCUSSION AND POSSIBLE ADOPTION OF OPINIONS ON:

5.1. Econase XT (FAD-2007-0020 under Regulation (EC) No 1831/2003; GMO/FEEDAP co-opinion)

Introduction

Within the framework of Regulation (EC) No 1831/2003 on additives for use in animal nutrition, EFSA has been requested to deliver an opinion on the efficacy and the safety for the target animals, the consumer, user and the environment of the product Econase XT P/L which is a preparation of beta-1,4-xylanase produced by the genetically modified micro-organism *Trichoderma reesei* (CBS 114044) when used under the proposed conditions.

Discussion

The GMO Panel has been asked to perform the assessment of the GM aspects of the microorganism used for the production of this feed enzyme. The FEEDAP Panel will assess all other parts of the feed enzyme application.

Econase XT is an enzyme feed additive with endo-1,4-beta-xylanase as its declared activity. The production strain for Econase XT is genetically modified *Trichoderma reesei*. No DNA sequences causing concern have been introduced in the production organism. The final enzyme preparations contain no cultivable producer organisms and no antimicrobial activity or mycotoxins in concentrations sufficient to cause concern. The absence of DNA from either the fermentation product or the final formulations was not examined. Since no sequences which cause concern are introduced in the final production strain the potential presence of low concentrations of recombinant DNA in the final product does not raise any particular safety concern.

Adoption

The opinion with regard to the risk assessment of the genetic modification of the application was adopted unanimously by the Panel. Once the other part has been adopted by the FEEDAP Panel, the co-opinion will be published on the EFSA website at:

http://www.efsa.europa.eu/en/science/gmo/gmo_opinions.html.

6. UPDATE ON APPLICATIONS RECEIVED UNDER DIRECTIVE 2001/18/EC, REGULATION (EC) NO 1829/2003 AND REGULATION (EC) NO 1831/2003

Ongoing applications

- NK603 maize for cultivation (Application NL-2005-22): the Spanish Competent Authority gave an opinion on the dossier, particularly on the environmental risk assessment of NK603 maize in accordance with Articles 6.3(c) and 19.3(c) of Regulation (EC) No 1829/2003. Four delegates of the Spanish Competent Authority presented the environmental risk assessment report to the GMO Panel. The Panel thanked the Spanish Competent Authority for the high quality report. The report of the Spanish Competent Authority will be included as an annex to the final opinion adopted by the Panel.
The Panel also discussed the possibility to hold a consultation with the European Commission in order to identify the most suitable legislative framework for issues related to cultivation practices of herbicide-tolerant crops, in particular, the effect of the herbicide treatment on biodiversity.
The Panel identified questions to the applicant for additional information with respect to the environmental risk assessment; these questions will be sent out after further consultation with the Spanish Competent Authority.
- 1507x59122 maize (Application NL-2005-15): questions to the applicant for additional information on the food/feed safety of 1507x59122 maize were identified by the Panel and discussed.
- MON89788 soybean (Application NL-2006-36): it was agreed that the data allow the Panel to continue with the safety evaluation.

In case additional information is requested to the applicant, the assessment procedure is kept on hold (the clock is stopped).

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

7.1. Non-authorised GM maize event DAS 59132 – Request for scientific advice from the Commission

EFSA received a letter from the European Commission, dated 14th March 2008, requesting scientific advice on the issue of potential contamination of US maize by the genetically modified DAS 59132 maize, which has not been authorized for release in the EU markets.

The Commission has provided scientific documentation related to genetically modified DAS 59132 maize and requested EFSA to consider the information with the view to identify specific risks that could lead the European Commission to consider specific management measures.

The special Task Force established previously for a contamination situation (see item 8 of the minutes of the 28th Plenary meeting⁴) has presented its work plan and the progress in the evaluation of the available data. An opinion will be drafted by the Task Force and submitted to the Panel at the next Plenary meeting.

⁴ http://www.efsa.europa.eu/EFSA/efsa_locale-1178620753812_1178620775210.htm

8. UPDATE ON SELF TASKING ACTIVITIES AND GUIDANCE ON GMO RISK ASSESSMENT

8.1. EC guidelines and update EFSA guidance document

DG SANCO stressed that the adoption of safety assessment guidelines was a priority for the European Commission and indicated its intentions to initiate consultation with Member States without delay. The Panel indicated that intensive work was ongoing on the update of the EFSA Guidance Document (which will be used as a starting point for the establishing of EC guidelines) and that updated Guidance should be ready for adoption at the next Plenary meeting.

8.2. Statistical considerations in the safety evaluation of GMOs

Members of the Working Group met on 31 March 2008. During this meeting the draft report was further developed before submission to the Panel. Some points of the report are still under discussion, but a short version will be provided to the Panel for the updating of the EFSA Guidance Document.

8.3. Allergenicity assessment of GM foods

A Working Group meeting took place on 7 April 2008. Since the draft document is in an advanced stage of development, the aim is to present it to the Panel by the end of the summer, in order to adopt it for public consultation and finalise an opinion by the end of the year.

Within the frame of the allergenicity assessment of GMO applications, a visit to the Joint Research Centre (JRC) of the European Commission was organized on 8 April 2008 to test the GMO DNA sequence database integrated with bioinformatics tools for similarity searches (see item 9 of the minutes of the 39th Plenary meeting⁵).

8.4. Guidance for the assessment of GM plants used for non-food/feed purposes

The comments received from the European Commission (DG ENV and DG SANCO) and the European Medicines Agency (EMA) were incorporated in the draft opinion on 'the risk assessment of GM plants used for non-food or non-feed purposes' that was adopted by the Panel at its 37th Plenary meeting of 22-23 November 2007 (see item 5.1 of the minutes of the 37th Plenary meeting⁶). The aim of the Working Group is to present the case studies work document to the Panel during the next Plenary before proceeding with the public consultation of the adopted opinion.

8.5. Assessment of the impacts of GM plants on non-target organisms

The Panel was informed that a final mandate has been signed. The first official Working Group meeting will be held on 30 April 2008.

⁵ http://www.efsa.europa.eu/EFSA/efsa_locale-1178620753812_1178681574436.htm

⁶ http://www.efsa.europa.eu/EFSA/efsa_locale-1178620753812_1178636421388.htm

9. FEEDBACK FROM EFSA AND THE SCIENTIFIC COMMITTEE

No feedback from EFSA and the Scientific Committee.

10. FEEDBACK FROM THE COMMISSION

The Panel was informed about the meeting of the OECD Task Force for the Safety of Novel Foods and Feeds held on 8-10 April 2008, during which Gijs Kleter, as a GMO Panel member, gave a presentation of the Animal Feeding Trial Report on behalf of EFSA. EFSA and the European Commission have been asked to draft a short document on the proposed modifications to the existing 90-day toxicity protocol. The Commission will be pleased to work together with the Panel in order to finalise a common document to present to the next OECD Task Force meeting.

11. DATES OF FUTURE MEETINGS

Meeting dates were agreed at earlier Plenary meetings.

12. ANY OTHER BUSINESS

The Panel was informed on the state of the Order adopted by France which suspends the cultivation of MON 810 maize. This Order was notified to the Commission as a safeguard measure under Article 23 of Directive 2001/18/EC and as an emergency measure under Article 34 of Regulation (EC) No 1829/2003. Following the Commission's request for assessment, EFSA had sent a letter indicating that the Panel would have provided a finalized scientific opinion by the end of April 2008, subject to the receipt of a comprehensive scientific data package and further justification of the position of France. This information is however still pending. This issue will be further discussed within the next environment Working Group, with the aim to produce a first draft opinion to be presented to the Panel during the next Plenary. Furthermore, the Panel would be in favour of having a meeting with the French scientific experts, involved in the French measure, to clarify any outstanding points, provided the prior receipt of all the relevant data from the French Competent Authority.

The Panel was informed about the public consultation of the BIOHAZ Panel's Opinion on "Foodborne antimicrobial resistance as a biological hazard". Comments from the Panel were discussed and will be submitted during the public consultation period.

Draft templates for website minutes of applications Working Group meetings have been presented to the Panel.