



# European Food Safety Authority

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## MINUTES OF THE 8<sup>TH</sup> PLENARY MEETING OF THE SCIENTIFIC PANEL ON GENETICALLY MODIFIED ORGANISMS HELD ON 3 AND 4 MARCH 2004 (ADOPTED ON 2 APRIL 2004)

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### PARTICIPANTS

#### *GMO Panel:*

Hans Christer Andersson, Detlef Bartsch, Hans-Joerg Buhk, Howard Davies, Marc De Loose, Michael Gasson, Niels Hendriksen, Sirpa Kärenlampi, Ilona Kryspin-Sorensen, Harry Kuiper (Chair), Marco Nuti, Fergal O'Gara (Vice-Chair), George Sakellaris, Joachim Schiemann, Willem Seinen, Angela Sessitsch, Jeremy Sweet (Vice-Chair), Jan Dirk Van Elsas and Jean-Michel Wal

#### *Ad Hoc experts:*

Tony Hardy<sup>1</sup> (PPR Panel), Richard Phipps<sup>1</sup> (University of Reading)

#### *EFSA:*

Suzy Renckens (scientific co-ordinator GMO Panel), Ellen Van Haver (assistant scientific co-ordination GMO Panel)

#### *European Commission:*

Dyanna Bennink<sup>2</sup> (DG RTD), Andreas Klepsch<sup>3</sup> (DG SANCO), Michael Walsh<sup>4</sup> (DG SANCO D5 – Interface unit), Barbara Weber<sup>5</sup> (DG ENV)

### INVITEES

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<sup>1</sup> Present 4 March

<sup>2</sup> Present 4 March a.m.

<sup>3</sup> Present 3&4 March p.m.

<sup>4</sup> Present 4 March p.m.

<sup>5</sup> Present 3&4 March a.m.

*Invited for agenda item 7:*

Helmut Gaugitsch (Federal Environment Agency, Vienna), Armin Spök (Inter-University Research Centre for Technology, Work and Culture, Graz), Rudolf Valenta (Department of Pathophysiology, University of Vienna)

*Invited for agenda item 8:*

Pieter Windels (Centre for Agricultural Research, Department for Plant Genetics and Breeding at Melle, Belgium)

## **APOLOGIES**

*GMO Panel:*

Colin Hill and Pere Puigdomenech Rosell

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### **1. WELCOME AND APOLOGIES FOR ABSENCE**

The Chairman opened the meeting and welcomed all. Apologies for absence were received from Colin Hill and Pere Puigdomenech Rosell.

### **2. ADOPTION OF THE AGENDA**

The agenda was adopted as proposed.

### **3. DECLARATION OF INTERESTS**

Declarations of interests with regard to the GM maize MON863, MON863xMON810 applications were noted during the 5<sup>th</sup> Plenary meeting:

[http://www.efsa.eu.int/science/gmo/gmo\\_meetings/168/minutes\\_gmo\\_05\\_final\\_en1.pdf](http://www.efsa.eu.int/science/gmo/gmo_meetings/168/minutes_gmo_05_final_en1.pdf)

No interests were declared for the other agenda items.

### **4. ADOPTION OF THE MINUTES OF THE 7<sup>TH</sup> PLENARY MEETING OF THE GMO PANEL**

The minutes of the 7<sup>th</sup> plenary meeting (held on 10-11 February 2004) were adopted, subject to a few changes proposed by the Panel. The minutes of this meeting are published at:

[http://www.efsa.eu.int/science/gmo/gmo\\_meetings/166/minutes\\_gmo\\_07\\_en1.pdf](http://www.efsa.eu.int/science/gmo/gmo_meetings/166/minutes_gmo_07_en1.pdf)

### **5. DISCUSSION AND POSSIBLE ADOPTION OF OPINIONS ON:**

#### **5.1. Self tasking activity on antibiotic resistance markers**

A revised version of the opinion on the use of antibiotic resistance genes as marker genes in genetically modified plants was distributed during the meeting. The rapporteur gave an overview of the progress made since the last plenary meeting. Because of the limited timeframe, the possible adoption of this opinion was deferred to the next plenary meeting.

## **5.2. Two questions from the Commission on GM maize MON863, MON863xMON810 (applications under 258/97 and 2001/18)**

The Panel considered the answers received from the applicant to the questions identified during the last plenary meeting. The Panel also considered the extent to which data for single insert lines MON863 and MON810 allow to draw conclusions about the MON863xMON810 hybrid.

## **6. PROGRESS REPORT ON:**

### **6.1. Question from Commission regarding guidance for GM food and feed applications under Regulation (EC) 1829/2003**

*Guidance document on GM plants and derived food and feed*

For this agenda item, *ad hoc* experts of the working group on GM food/feed guidance were invited as well. The rapporteur reported on the progress made since the last meeting of the working group held on 17 February 2004. The Panel discussed the guidance document and identified some action items for the next working group meeting scheduled for 19 March 2004. The draft guidance document will have to be adopted at the next plenary meeting before it will be published on the EFSA website for public consultation. The Panel will consider the written comments received from the public and discuss them during a stakeholder consultation on 25 May 2004.

*Guidance document on GM micro-organisms (GMM) and derived food and feed*

The guidance document for genetically modified micro-organisms (GMM) and derived food and feed was discussed during a working group meeting held on 12 March 2004. The main outcome of that meeting was to clarify the scope of Regulation 1829/2003 on GM food and feed and, accordingly, the scope of the guidance document to be drafted by EFSA.

### **6.2. Update of terms of reference for self tasking activities**

The Panel members were informed about the progress made on the proposal for self tasking activity on “Post Market Environmental Monitoring (PMEM)”. The Executive Director supports the envisaged activity. EFSA will inform DG Environment about the objective of this exercise, i.e. to develop guidance for the scientific evaluation and elaboration of a PMEM plan. EFSA was informed that a working group of the Competent Authorities for Directive 2001/18/EC will initiate work on the management part of this issue and will propose to collaborate with that group.

## **7. PRESENTATION ON THE RISK ASSESSMENT OF GM FOODS BY AUSTRIAN EXPERTS**

In November, EFSA received an invitation for a GMO expert from the Authority or the GMO Panel to participate in the workshop ‘Scrutinizing GMO Risk Assessment. Evaluating the practice of risk assessment of genetically modified plants and food in the EU’ organised by the Austrian Federal

Environment Agency and the Inter-University Research Centre for Technology, Work and Culture that was held in Vienna on 10 December 2003. As no expert was found in a position to attend that workshop, the Panel decided to invite the organisers of that workshop to give a presentation on the outcome of the study ‘Toxikologie und Allergologie von GVO-Produkten’ to a plenary meeting of the GMO panel. Helmut Gaugitsch, Armin Spök and Rudolf Valenta respectively elaborated on specific aspects of the risk assessment, with particular focus on toxicity and allergenicity issues. The presentation was followed by a discussion between the Austrian experts and Panel members.

## **8. ANY OTHER BUSINESS**

### *Presentation on T-DNA integration into plant genomes*

Pieter Windels, a researcher at the Centre for Agricultural Research at Melle, Belgium, was invited to the plenary meeting to give a presentation on “Integration of exogenous DNA into plant chromosomes. Use of plant/T-DNA junctions”.

### *Questions from stakeholders*

The Panel was informed about e-mails received by EFSA regarding questions and comments on the opinion of GM oilseed rape GT73 that was recently released on the EFSA website.

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