



**MINUTES OF THE 17<sup>TH</sup> PLENARY MEETING OF THE  
SCIENTIFIC PANEL ON GENETICALLY MODIFIED ORGANISMS  
HELD ON 2-4 MARCH 2005  
(ADOPTED ON 20 APRIL 2005)**

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## **PARTICIPANTS**

### *GMO Panel:*

Hans Christer Andersson<sup>1</sup>, Detlef Bartsch, Howard Davies, Niels Bohse Hendriksen, John Heritage<sup>2</sup>, Sirpa Kärenlampi, Ilona Kryspin-Sorensen, Harry Kuiper (Chair), Pere Puigdomenech<sup>2</sup>, Joachim Schiemann, Willem Seinen, Jeremy Sweet (Vice-Chair), Jan Dick Van Elsas<sup>1</sup> and Jean-Michel Wal

### *EFSA:*

Anna Christodoulidou (scientific officer), Karine Lheureux (scientific officer), Luisa Mannu (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)

## **APOLOGIES**

### *GMO Panel:*

Hans-Joerg Buhk, Marc De Loose, Michael Gasson, Marco Nuti, Fergal O’Gara, George Sakellaris and 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.

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<sup>1</sup> Not present on 2 March.

<sup>2</sup> Not present on 4 March.

As regards new applications (Maize 59122<sup>3</sup>, potato EH92-527-1<sup>4</sup> and MS8xRF3<sup>5</sup>), 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. Regarding the MS8xRF3 application, two experts<sup>6</sup> declared that their institute by which they are/were employed conducted biosafety studies on MS8xRF3 oilseed rape. These experts will therefore abstain from voting on this opinion.

#### **4. ADOPTION OF THE MINUTES OF THE 16TH PLENARY MEETING HELD ON 18-19 JANUARY 2005**

The minutes of the 16<sup>th</sup> plenary meeting (18-19 January 2005) were adopted as proposed. The minutes of this meeting are published at:

[http://www.efsa.eu.int/science/gmo/gmo\\_meetings/773/gmo\\_16th\\_plenmeet\\_minutes1.pdf](http://www.efsa.eu.int/science/gmo/gmo_meetings/773/gmo_16th_plenmeet_minutes1.pdf).

#### **5. FEEDBACK FROM AND TO THE SCIENTIFIC COMMITTEE**

The Chair gave an overview of the outcome of the 11<sup>th</sup> Plenary meeting of the EFSA Scientific Committee held on 28 February – 1 March 2005. The minutes of this meeting are published at:

[http://www.efsa.eu.int/science/sc\\_committee/sc\\_meetings/810/scm\\_11th\\_plenmeet\\_minutes1.pdf](http://www.efsa.eu.int/science/sc_committee/sc_meetings/810/scm_11th_plenmeet_minutes1.pdf).

#### **6. DISCUSSION AND POSSIBLE ADOPTION OF OPINION ON:**

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

The Panel identified some aspects of the general surveillance plan for Bt11 maize to be clarified and modified by the applicant in order to bring them in line with regulatory requirements.

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<sup>3</sup> 59122 maize: declarations were made by Hans-Joerg Buhk, Gijs Kleter, Harry Kuiper and Joachim Schiemann.

<sup>4</sup> EH92-527-1 potato: declarations were made by Christer Andersson, Hans-Joerg Buhk, Gijs Kleter, Harry Kuiper and Joachim Schiemann.

<sup>5</sup> MS8xRF3 oilseed rape: declarations were made by Hans-Joerg Buhk, Marc de Loose, Gijs Kleter, Harry Kuiper and Joachim Schiemann.

<sup>6</sup> Marc de Loose and Jeremy Sweet.

## **7. PROGRESS REPORTS ON:**

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

This item was discussed together with item 9.4. The Panel identified some issues regarding the molecular characterisation, food/feed safety aspects and the environmental risk assessment of LLRice62 to be further clarified by the applicant.

### **7.2. 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 1 February 2005 was presented to the Panel.

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 in view of a possible adoption at the next plenary meeting.

### **7.3. 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 third stakeholder 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, held on 20 January 2005. The minutes will be published on the EFSA-website.

### **7.4. Self tasking activity on animal feeding trials**

A follow-up of the first working group meeting on animal feeding trials held on 24 January 2005 was presented to the Panel. Different tasks have been attributed to different rapporteurs of the working group.

## **8. NEW REQUESTS FROM COMMISSION: DISCUSSION AND ADOPTION OF MANDATES**

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

EFSA received from the Commission a request for a scientific opinion on GM oilseed rape MS8, RF3 and MS8xRF3 introduced under Directive 2001/18/EC (EFSA-Q-2005-003). EFSA will seek clarification from the applicant and the Commission regarding the scope of the application and the terms of reference received from the Commission. As stated in the request provided to the Commission, the applicant is not longer interested in cultivation and the rapporteur Member State has suggested the possible exclusion of cultivation as a condition for consent of Ms8, Rf3 and Ms8 x Rf3.

## **8.2. Question from Commission regarding GM potato EH92-527-1 (application C/SE/96/3501 under 2001/18)**

EFSA received from the Commission a request for a scientific opinion on GM potato EH92-527-1 introduced under Directive 2001/18/EC (EFSA-Q-2005-023) for cultivation and production of starch.

## **9. UPDATE ON APPLICATIONS RECEIVED UNDER REGULATION 1829/2003**

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

*New application (under completeness check):*  
EFSA-GMO-UK-2005-12: GM Maize 59122

The summary of the application can be found on the following website:  
[http://www.efsa.eu.int/science/gmo/gm\\_ff\\_applications/catindex\\_en.html](http://www.efsa.eu.int/science/gmo/gm_ff_applications/catindex_en.html).

## **10. APPOINTMENT OF RAPPORTEURS FOR NEW QUESTIONS**

Rapporteurs have been appointed for the new applications mentioned under item 9.

## **11. STAKEHOLDER ISSUES**

The Panel was informed about the different requests for public access to applications or certain parts of the applications.

Following the requirements of Regulation (EC) 1049/2001 for request for public access, EFSA shall in case of doubt consult with third-parties on the applicability of Article 4(4) of Regulation (EC) 1049/2001. After consultation, EFSA gives access to the non-confidential parts of the application to the person who has requested public access. In view of Article 30 of Regulation (EC) 1829/2003 EFSA has to reserve its position on the parts the applicant has claimed confidential until the Commission after consultation with the applicant has determined which information shall be kept confidential. Access is given for an initial period of two weeks. It is systematically reminded that all persons reproducing, redistributing, or making commercial use of this information are expected to adhere to the terms and conditions asserted by the copyright holder.

## **12. DATES OF FUTURE MEETINGS**

There were no new dates for future meetings.

### **13. ANY OTHER BUSINESS**

The Panel had a discussion on the issue of Panel members being approached by stakeholders, and in particular by journalists. In this regard, “Media handling guidelines for the Scientific Committee and the Panels” have been distributed to the Panel.

Following the 16<sup>th</sup> Plenary meeting, the Panel had a further discussion on the mandate of new self tasking activity on the production of plant made pharmaceuticals in genetically modified crops.

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