

**MINUTES OF THE 53<sup>RD</sup> PLENARY MEETING OF THE  
SCIENTIFIC PANEL ON GENETICALLY MODIFIED ORGANISMS  
HELD ON 21-22 OCTOBER 2009 IN PARMA, ITALY  
(ADOPTED ON 2 DECEMBER 2009)**

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## **PARTICIPANTS**

### *GMO Panel:*

Hans Christer Andersson, Salvatore Arpaia, Detlef Bartsch<sup>1</sup>, Josep Casacuberta, Gerhard Flachowsky, Patrick du Jardin, Huw Jones, Lieve Herman, Sirpa Kärenlampi, Jozsef Kiss<sup>1</sup>, Gijs Kleter, Harry Kuiper (Chair), Antoine Messéan<sup>1</sup>, Kaare Nielsen, Joe Perry, Annette Pöting, Jeremy Sweet, Christoph Tebbe, Atte Von Wright and Jean-Michel Wal<sup>1</sup>.

### *EFSA:*

GMO Unit: Per Bergman, Anna Christodoulidou, Zoltán Divéki, Antonio Fernández, Andrea Germini, Ana Gomes, Yi Liu, Sylvie Mestdagh, Claudia Paoletti, Nancy Podevin, Ellen Van Haver, Elisabeth Waigmann.

### *European Commission:*

Kaja Kantorska, Eleftheria Nearchou, Sabine Pelsser and Michael Walsh (DG SANCO); Bernadette Murray (DG ENV).

## **APOLOGIES**

### *GMO Panel:*

Howard Davies.

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

The Chair welcomed the participants. Apologies were received from one Panel member listed above.

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

The agenda was adopted without changes.

## **3. DECLARATION OF INTERESTS**

In accordance with EFSA's Policy on Declarations of Interests, EFSA screened the Annual Declaration of interest (ADoI) and Specific Declaration of interest (SDoI) filled in by the experts invited for the present meeting. No conflicts of interests related to the issues discussed in this meeting have been identified during the screening process or at the beginning of this meeting.

## **4. ADOPTION OF THE MINUTES OF THE 52<sup>ND</sup> PLENARY MEETING HELD ON 9-10 SEPTEMBER 2009**

The minutes of the 52<sup>nd</sup> Plenary meeting (9-10 September 2009) were adopted with small modifications and will be published at: [http://www.efsa.europa.eu/EFSA/efsa\\_locale-1178620753812\\_1211902926923.htm](http://www.efsa.europa.eu/EFSA/efsa_locale-1178620753812_1211902926923.htm)

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<sup>1</sup> Only present on 21 October 2009

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

### **5.1. FINASE EC (6-phytase) for chickens for fattening/ chickens for laying; laying hens; turkeys for fattening/ turkeys for breeding; piglets (weaned); pigs for fattening; sows; ducks and other minor poultry species (i.e. geese, quail, pigeon, pheasants and other game birds) (Q-2009-00676).**

#### *Introduction*

Following a request from the European Commission, the European Food Safety Authority (EFSA) was asked to deliver a scientific opinion on the safety and efficacy of Finase® EC (6-phytase) as feed additive for: chickens for fattening and reared for laying, laying hens, turkeys for fattening and reared for breeding, ducks and other minor poultry species, piglets (weaned), pigs for fattening and sows.

#### *Discussion*

Finase® EC is a feed additive with 6-phytase as its declared enzymatic activity. The production strain for Finase® EC is a genetically modified fungus *Trichoderma reesei*. The final enzyme preparations contain no cultivable production organisms or recombinant DNA above the limits of detection. The products do not have antimicrobial activity or mycotoxins.

#### *Adoption*

The opinion was adopted unanimously by the EFSA GMO Panel. The scientific opinion will be published on the following EFSA website: [http://www.efsa.europa.eu/EFSA/efsa\\_locale-1178620753812\\_ScientificDocuments.htm](http://www.efsa.europa.eu/EFSA/efsa_locale-1178620753812_ScientificDocuments.htm)

### **5.2. Self-mandate on Assessment of allergenicity of genetically modified foods (EFSA-Q-2005-125)**

During the Plenary meeting of 9-10 September 2009, the previous draft of the report of the self mandate on the assessment of allergenicity of GM foods was presented to the EFSA GMO Panel. The revised draft was subsequently forwarded to the EFSA NDA Panel and Scientific Committee for possible comments. Comments were received from some members of the NDA Panel and there was a general agreement on the conclusions and recommendations of the document.

The draft report was adopted by the EFSA GMO Panel with the aim of launching it for public consultation for a period of 2 months.

## **6. DISCUSSION OF OPINIONS**

None.

## **7. UPDATE ON APPLICATIONS RECEIVED UNDER REGULATION (EC) NO 1829/2003 AND REGULATION (EC) NO 1831/2003**

The Scientific Opinion on an application for authorisation of genetically modified maize Bt11xGA21 for food and feed uses, import and processing submitted under Regulation (EC) No. 1829/2003 (EFSA-GMO-UK-2007-49) was adopted by written procedure on 15 September 2009 by the EFSA GMO Panel.

## **8. NEW REQUESTS TO EFSA: DISCUSSION AND ADOPTION OF MANDATES**

### **8.1. Applications under Regulation (EC) No 1829/2003**

Two new applications have been received:

- Application for authorisation of genetically modified soybean MON 87701 x MON 89788 for food and feed uses, import and processing from Monsanto (EFSA-GMO-NL-2009-73).
- Application for authorisation for marketing Novo yeast cream (pAK1214) as feed for pigs from Novo Nordisk (EFSA/GMO/DK/2009/74).

Competent Authorities of the Member States within the meaning of Directive 2001/18/EC as foreseen by Articles 6 (4) and 18 (4) of Regulation (EC) No 1829/2003 will be consulted by EFSA once the above mentioned applications are valid. On its own initiative EFSA has broadened this consultation also to Member States' National Competent Authorities under Regulation (EC) No 1829/2003 and other national risk assessment bodies. The comments will be considered during the scientific evaluation by the EFSA GMO Panel of the risk assessment performed by the applicant.

The summary of these applications, as well as the information on their current status can be found on Register of Questions under the respective question numbers: <http://registerofquestions.efsa.europa.eu/roqFrontend/questionsList.jsf>.

### **8.2. Applications under Regulation (EC) No 1831/2003**

None

### **8.3. Other mandates**

#### **a) General GMO ban from Portugal (EFSA-Q-2009-00851).**

The Republic of Portugal has informed the European Commission of its intention to declare the Autonomous Region of Madeira as an area free of cultivation of varieties of GMOs. Following this notification, the Commission has requested EFSA, under Article 29(1) and in accordance with Article 22(5) of Regulation (EC) No 178/2002, to provide a scientific opinion on the evidence submitted by Portugal at the latest on 31 January 2010. The opinion must assess, in light of the requirements of Article 95(5) of the EC Treaty, whether the particular scientific evidence relates to the protection of the environment in the concerned area.

#### **b) EC mandate on LLRice62 and consequences on gene flow**

##### *Introduction*

On 6 August 2009, the European Commission requested the EFSA GMO Panel to review the recently published scientific paper of Lu & Yang (2009) on gene flow from GM rice to its wild

relatives<sup>2</sup> and to indicate whether this paper contains new information that would alter the EFSA GMO Panel environmental safety conclusions on LLRice62 (EFSA/GMO/UK/2004/04), for which EFSA issued a scientific opinion in 2007. This issue was also discussed during the meeting EFSA organised with NGOs on 2 October 2009 (see item 10).

### *Discussion and conclusion*

In line with its previously published scientific opinion, the EFSA GMO Panel reiterates that appropriate management measures should be in place to restrict viable LLRice62 grains potentially being spilled into EU rice growing areas. In addition, operators should report any grain spillage of GMHT rice in areas adjacent to cultivated land used for rice production, and report on the efficacy of measures to remove or destroy any subsequent escaped GMHT plants. The EFSA GMO Panel notes that the post-market environmental monitoring plan provided by the applicant is in line with the intended uses of LLRice62.

In light of the scientific paper provided by the European Commission and, having considered this and other relevant scientific publications on vertical gene flow in rice, the EFSA GMO Panel concludes that, in terms of risk to the environment, no new scientific evidence has been provided that invalidates the previous environmental risk assessment evaluation of LLRice62 for its intended uses, which exclude cultivation.

### *Adoption*

The document was adopted unanimously by the EFSA GMO Panel. The adopted scientific opinion will be published as a statement on the following EFSA website: [http://www.efsa.europa.eu/EFSA/efsa\\_locale-1178620753812\\_ScientificDocuments.htm](http://www.efsa.europa.eu/EFSA/efsa_locale-1178620753812_ScientificDocuments.htm)

#### **c) EC request on public comments on MON 810 maize**

The European Commission requested EFSA to assess the comments from the public submitted to the European Commission on the scientific opinion of application EFSA-GMO-RX-MON 810 (maize MON 810) and ‘to indicate whether they contain new scientific elements that could lead the GMO Panel to reconsider the outcome of its opinion’.

Comments raised by the public and not already addressed in the scientific opinion of the EFSA GMO Panel or in its specific responses to comments raised by Member States, will be scrutinised by the respective working groups. Environmental issues have been discussed during the meeting with environmental NGOs held on 2 October 2009 (see item 10). The European Commission expects an answer before the end of November.

#### **d) EC request concerning the safety of SNP in 1507 maize**

The European Commission has requested EFSA to analyse the possible consequences of a single nucleotide substitution in the 35S promoter present in 1507 maize, which has recently been reported in Nature Biotechnology<sup>3</sup>.

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<sup>2</sup> Lu BR, Yang C, 2009. Gene flow from genetically modified rice to its wild relatives: Assessing potential ecological consequences. *Biotechnology Advances*, 27: 1083-1091.

<sup>3</sup> Morisset D, Demisar T, Gruden K, Vojvoda J, Stebih D, Zel J (2009) Detection of genetically modified organisms – closing the gaps. *Nature Biotechnology* 27(3): 700-1.

The EFSA GMO Panel scrutinised this paper and concluded that this reported single nucleotide difference between the original plasmid used for transformation and the sequence in maize event 1507 reported is extremely unlikely to raise any safety concern. However, EFSA will also send a letter to the respective applicants with a question to clarify whether this SNP is also present in other applications containing the 1507 event.

## **9. UPDATE ON SELF MANDATE ACTIVITIES AND GUIDANCE FOR GMO RISK ASSESSMENT**

### **a) Self mandate on choice of comparator**

The working group will have its next meeting 28<sup>th</sup> of October. A first draft document will be presented at the December plenary meeting.

### **b) Self mandate to update the GMM guidance**

The next meeting is scheduled for 17-18 December 2009. A member of the CEF Panel has joined the working group.

### **c) Self mandate on Non-Target Organisms**

The Chair of the self mandate working group on environmental impacts of GM plants on non-target organisms gave a presentation on the present status of the draft document. The working group will develop a specific NTO Guidance for incorporation into the updated ERA guidance document.

### **d) Mandate for updating the environmental risk assessment section of the EFSA Guidance document**

The Chairs of the working groups (sub ERA Guidance Document and NTO) for updating the environmental risk assessment of the EFSA guidance document presented to the EFSA GMO Panel the current status of the document. The draft document will be presented to the EFSA GMO Panel at its December plenary meeting for possible adoption, prior to the launch of a public consultation by mid December 2009.

### **e) Mandate for guidance on GM animals**

A member of the working group on human health safety assessment of GM animals gave a brief introduction of the draft guidance document related to molecular characterisation and food/feed safety aspects. A final draft will be presented to the EFSA GMO Panel at its December plenary meeting. The EFSA GMO Panel was also informed about the working group for developing guidance on environmental risk assessment of GM animals, as well as about the status of the tenders for GM fish, insects, mammals and birds.

## **10. FEEDBACK FROM EFSA AND THE SCIENTIFIC COMMITTEE**

The Head of the EFSA's GMO Unit reported on the EFSA conference on the risk assessment of GMOs for human and animal health and the environment, held on 14-15 September 2009. The report and presentations of the conference can be downloaded from the EFSA website: [http://www.efsa.europa.eu/EFSA/efsa\\_locale-1178620753812\\_1211902768091.htm](http://www.efsa.europa.eu/EFSA/efsa_locale-1178620753812_1211902768091.htm).

EFSA has held a meeting with environmental NGOs on 2 October 2009. Five EFSA GMO Panel members and representatives of Global 2000/Friends of the Earth and Greenpeace participated to this meeting. Discussions focused on recent issues linked to the GM maize MON 810 and the GM rice LLRice62. The meeting included an exchange of views on the scientific comments received on the risk assessment of MON 810 during the Commission's public consultation (see also item 8.3.c) and the scientific questions following the EC request on the safety of LLRice62 and the consequences on gene flow (see also item 8.3.b). Additional topics discussed were EFSA's review of long-term environmental risk assessment and its review of the environmental impacts of herbicide tolerant GM crops.

The Panel was informed about the outcome of the 38<sup>th</sup> Plenary meeting of the Scientific Committee held on 29-30 September 2009. The minutes of this meeting will be published at: [http://www.efsa.europa.eu/EFSA/efsa\\_locale-1178620753812\\_1211902897021.htm](http://www.efsa.europa.eu/EFSA/efsa_locale-1178620753812_1211902897021.htm).

## **11. FEEDBACK FROM THE COMMISSION**

The Commission representative informed the EFSA GMO Panel about the status of applications that have been presented to the Standing Committee on the Food Chain and Animal Health (19 October) and to the Agriculture Council (19-20 October) for possible authorisation, and for which no qualified majority was reached. The EC representative also informed the EFSA GMO Panel that the Austrian delegation informed the Standing Committee of certain shortcomings in the study on "Biological effects of transgenic maize NK603 x MON 810 fed in long term reproduction studies in mice"<sup>4</sup> that was previously commissioned by the Austrian Federal Ministry of Health, Family and Youth. The EFSA GMO Panel has commented previously on this report and no conclusions could be drawn on the basis of the data provided (see item 13 of the minutes of the 46<sup>th</sup> GMO Panel's plenary meeting<sup>5</sup>).

## **12. DATE AND PLACE OF FUTURE MEETINGS**

Meeting dates were agreed at earlier plenary meetings.

## **13. ANY OTHER BUSINESS**

EFSA has been asked to assist the European Commission in answering the comments from EuropaBio and France on the draft EC guidelines on the risk assessment of GM food and feed. Comments relate to molecular characterisation and food/feed safety aspects, and will be discussed in the respective working groups.

The EFSA GMO Panel was informed about new features of the application status table on the GMO Scientific Extranet, which is restricted to GMO Panel members and members of the Working Groups dealing with applications.

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<sup>4</sup> [http://ec.europa.eu/food/committees/regulatory/scfcah/modif\\_genet/sum\\_19102009\\_en.pdf](http://ec.europa.eu/food/committees/regulatory/scfcah/modif_genet/sum_19102009_en.pdf)

<sup>5</sup> [http://www.efsa.europa.eu/cs/BlobServer/Event\\_Meeting/gmo\\_minutes\\_46th\\_plenmeet\\_en,0.pdf?ssbinary=true](http://www.efsa.europa.eu/cs/BlobServer/Event_Meeting/gmo_minutes_46th_plenmeet_en,0.pdf?ssbinary=true)