# MINUTES OF THE 48TH PLENARY MEETING OF THE SCIENTIFIC PANEL ON GENETICALLY MODIFIED ORGANISMS HELD ON 11-12 MARCH 2009 IN PARMA, ITALY (ADOPTED ON 21 APRIL 2009)



## PARTICIPANTS

*GMO Panel:*
Hans Christer Andersson, Salvatore Arpaia, Howard Davies, Patrick du Jardin, Lieve Herman, Sirpa Kärenlampi, Jozsef Kiss, Gijs Kleter, Ilona Kryspin-Sorensen, Harry Kuiper (Chair), Joe Perry, Nickolas Panopoulos, Annette Pöting, Joachim Schiemann, Willem Seinen, Jeremy Sweet and Jean-Michel Wal.

*EFSA:*
Aguilera Jaime, Per Bergman, Anna Christodoulidou, Zoltán Divéki, Christina Ehlert, Andrea Germini, Ana Gomes, Karine Lheureux, Yi Liu, Sylvie Mestdagh, Claudia Paoletti, Claudia Parisi, Nancy Podevin, Reinhilde Schoonjans, Elisabeth Waigmann.

*European Commission:*
Michael Walsh and Sabine Pelsser (DG SANCO); Bernadette Murray (DG ENV)

**APOLOGIES**

*GMO Panel*: Detlef Bartsch, Josep Casacuberta, Niels Bohse Hendriksen, Ingolf Nes.

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## 1. WELCOME AND APOLOGIES FOR ABSENCE

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

## 2. ADOPTION OF THE AGENDA

The agenda was adopted as proposed.

## 3. DECLARATION OF INTERESTS

EFSA secretariat screened the ADoI and SDoI filled in by the scientific experts invited at this meeting in accordance with EFSA's Policy on Declarations of Interests.
With regard to this meeting no other interest than those already declared in the ADoI or in a previous SDoI and screened by EFSA in accordance with its Policy on Declarations of Interests and implementing documents thereof was declared by the experts.

## 4. ADOPTION OF THE MINUTES OF THE 47TH PLENARY MEETING HELD ON 28-29 JANUARY 2009

The minutes of the 47th Plenary meeting (28-29 January 2009) were reviewed and adopted. They are published at:
http://www.efsa.europa.eu/EFSA/efsa_locale-1178620753812_1211902296627.htm

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

### 5.1. Mandate for a consolidated opinion on use of antibiotic resistant genes (ARM) used as marker genes in genetically modified plants (EFSA-Q-2008-411)

*Introduction*

On 21 May 2008, the European Food Safety Authority (EFSA) received the request EFSA-Q-2008-411 by the European Commission (DG SANCO and DG ENV reference: D/510274) for a consolidated opinion on the use of ARM genes as marker genes in genetically modified plants in accordance with Article 29 of Regulation (EC) No 178/2002.

EFSA was asked to work in close collaboration with the European Medicines Agency (EMEA) and any other appropriate scientific institutes having recognised international expertise in the field of antibiotic resistance in order to characterise the use and importance of the antibiotics for which these genes encode resistance.

The opinion takes into account the previous opinions of the GMO Panel (EFSA, 2004; EFSA, 2007) and includes a risk assessment of the potential dissemination of antibiotic resistance marker genes from GM plants into bacteria based on current scientific knowledge. There is an increasing understanding of the origin, evolution and ecology of antibiotic resistance genes and this has been acknowledged in this scientific opinion.

The general principles for risk assessment of GM plants as expressed in the Directive 2001/18/EC of the European Parliament and of the Council (EC, 2001) and in the Guidance Document of the GMO Panel (EFSA, 2006) have been followed here. The following issues have been specifically addressed: 1) Identification of characteristics which may cause adverse effects (hazard identification); 2) Evaluation of the likelihood of functional gene transfer and evaluation of the potential consequences of the gene transfer, if it occurs (hazard characterisation) (Chapter 2, 3); and 3) Evaluation of the overall potential risk posed by the presence of antibiotic resistance marker genes in GM plant

*Discussion*

The opinion focuses on the two antibiotic resistance marker genes that are present in GM plants for which an application has been submitted to EFSA. One is functional in the plant (*aph(3')*-IIa = *npt*II, kanamycin/neomycin resistance); the other gene (*ant-(3'')*-Ia = *aad*A; streptomycin/spectinomycin resistance), is not expressed in the GM plants as the expression is regulated by a bacterial promoter not active in plants. The latter gene is used at the initial steps to develop the genetic constructs before introduction to the plant. An overview of relevant scientific literature is given and a qualitative risk assessment is provided. Whilst a detailed evaluation of *aph(3')*-IIa and *ant-(3'')*-Ia genes is included in the appendices, the opinion itself specifically addresses the indirect hazards.

*Adoption*

The GMO Panel thanked the GMO Panel members taking part of the joint drafting group for their extensive work and detailed scientific opinion. The text as proposed by the joint Working Group

was adopted by the GMO Panel with some editorial changes. Additionally, the GMO Panel agreed to amend the text upon the suggestions of the BIOHAZ Panel who had suggested some changes in the body text and the conclusions during their plenary meeting. This version was later submitted to the BIOHAZ Panel for final adoption.

The final co-opinion is published as part of the EFSA statement "Consolidated presentation of the joint Scientific Opinion of the GMO and BIOHAZ Panels on the "Use of Antibiotic Resistance Genes as Marker Genes in Genetically Modified Plants" and the Scientific Opinion of the GMO Panel on "Consequences of the Opinion on the Use of Antibiotic Resistance Genes as Marker Genes in Genetically Modified Plants on Previous EFSA Assessments of Individual GM Plants" http://www.efsa.europa.eu/EFSA/efsa_locale-1178620753812_1211902569473.htm.

### 5.2. New information submitted by Austria in context of Safeguard measure adopted under under Article 23 of Directive 2001/18/EC on oilseed rape GT73 (EFSA-Q-2008-315)

The GMO Panel was requested under Article 29(1) and in accordance with Article 22(5) of Regulation (EC) No 178/2002, to provide a scientific opinion as to "*whether, in accordance with Article 23 of Directive 2001/18/EC, the statement and documents submitted by the Austrian authorities comprise new or additional information affecting the environmental risk assessment, such that detailed grounds exist to consider that the above authorised GMO, for the uses laid down in the corresponding consent, constitute a risk to human health or the environment*".

In this context, and upon request of the European Commission/DG Environment, EFSA invited the Austrian scientists and representatives from the Competent Authority to present their arguments in support to their safeguard clause during a meeting with some members of the GMO Panel and EFSA staff. As a consequence of the various attempts to arrange such a bilateral meeting, the DG Environment delegation present at the GMO plenary meeting was consulted on how to proceed in light of the approaching deadline for this mandate. It was agreed to organise a bilateral meeting on the 23rd of April 2009.

### 5.3. New information submitted by Austria in the context of a safeguard measure adopted under Article 23 of Directive 2001/18/EC on oilseed rape lines Ms8, Rf3 and Ms8xRf3 (EFSA-Q-2008-743)

Idem as 5.2

### 5.4. Information submitted by Austria in support of a safeguard measure adopted under Article 23 of Directive 2001/18/EC on maize line MON863 (EFSA-Q-2008-742)

Idem as 5.2

## 6. DISCUSSION OF OPINION ON:

### 6.1. Scientific Opinion on Guidance for risk assessment of genetically modified plants used for non-food or non-feed purposes (EFSA-Q-2007-176)

In September 2004, EFSA published guidance for the preparation and presentation of GM plant applications submitted within the framework of Regulation (EC) No 1829/2003 on GM food and feed and of Directive 2001/18/EC on the deliberate release into the environment of GMOs. On 26 September 2005 EFSA agreed to initiate a self-tasking activity and mandated the EFSA GMO Panel to provide an opinion on guidance for the assessment of genetically modified plants used for non-food or non-feed purposes, to supplement the EFSA Guidance Document.

The Panel was provided with the draft opinion as amended after the public consultation. The Panel was informed about the way pubic comments have been processed: the main principles that were tabled during the public consultation were clarified and where needed, confirmed by the European Commission, and the text was amended accordingly. Panel members were invited to reflect on the principles of the risk assessment strategy and to provide comments if any to the GMO unit. The finalized scientific opinion on guidance will be submitted for adoption in the forthcoming plenary meeting.

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

### 7.1 Written adoption for authorisation of genetically modified GHB614-glyphosate tolerant Cotton and derived food and feed (EFSA-GMO-NL-2008-51) (EFSA-Q-2008-016)

The GMO Panel adopted on 10 March 2009 by written procedure the opinion on the Application (EFSA-GMO-NL-2008-51) for authorisation of genetically modified GHB614-glyphosate tolerant cotton and derived food and feed (EFSA-Q-2008-016).

The opinion was adopted unanimously by the GMO Panel. The scientific opinion is published on the following EFSA website: http://www.efsa.europa.eu/EFSA/efsa_locale-1178620753812_1211902368331.htm

The overall opinion, including the table containing the responses of the Panel to Member States is published in the Register of Questions EFSA-Q-2008-016: http://registerofquestions.efsa.europa.eu/roqFrontend/questionsList.jsf

### 7.2 Ongoing applications

- **Maize LY038 and derived food and feed (application EFSA-GMO-NL-2006-31 under Regulation (EC) No 1829/2003; EFSA-Q-2006-018)**: The application has been discussed with respect to the use of the negative segregant as comparator. The GMO Panel has decided to send a new set of questions to the applicant.

- **Presentation on ongoing procedures**: A discussion took place on the procedures and timelines to ask additional information from the applicants, which is currently done in 95% of the applications. The aim is to enhance the overall process and facilitate the organisation of the administrative work involved as well as the planning to handle all pending dossiers and deliver scientific opinions within the legal deadline of 6 months.

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

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

None.

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

Application for authorisation of L-Isoleucine - Feed Grade as a nutritional feed additive was received through the Competent Authorities of France under Regulation (EC) No 1831/2003 (EFSA-Q-2009-00456).
The summary of the application as well as the information on the current status can be found through the following webpage leading to EFSA's Register of Questions: http://registerofquestions.efsa.europa.eu/roqFrontend/

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

**Formal consultation on the normative EC Guidelines for food feed safety**

In response to the formal consultation of EFSA from the European Commission on the draft text which will be part of the legal framework for EFSA's GMO assessment, the Panel modified the document which will be sent officially to the Commission by the end of March. The Panel discussed also the response to the public comments. It was proposed to group the comments and provide general answers.

**Self-tasking on comparators**

The GMO Panel is facing questions linked to the selection of comparator(s) that applicants have started to use and to present in GMO applications. More questions may be encountered as the production of next-generation GM crops accelerates. In order to ensure a continued and harmonized risk assessment process, the current criteria for comparator selection must be further clarified. EFSA's hierarchy was informed about the need and the importance of this task for the core work of the Panel on applications. It was agreed that a draft mandate for a self-task will be prepared and submitted.

**Self-tasking on updating the GM Microorganisms Guidance Document**

The GMM Working Group members presented a draft proposal for the updating of the Guidance Document for the risk assessment of GM Microorganisms and their derived products intended for food and feed use. The need for this updating and for establishing a self-tasking Working Group was discussed. The Panel was of the opinion that the draft proposal should be improved by including the issues to be addressed, in order to justify the need for a self-tasking mandate.

**Self-tasking on allergenicity**

The Panel was updated on the progress of the self-tasking Working Group on allergenicity. The final chapters on analytical and profiling techniques and on the general Conclusions and recommendations are being elaborated and the document will be finalized after the forthcoming meeting of the Working Group on 1 April 2009.

**Self–tasking on Non-Target Organism**

At the EFSA scientific colloquium on Environmental risk assessment of GM plants in June 2007 (Tabiano), the different methods to assess the potential adverse effects of GM plants on non-target organisms were discussed with the scientific community. The EFSA self-tasking Working Group has subsequently worked on a proposal for a harmonized approach using the strengths of previous experiences and existing approaches. The draft working document will be discussed at the forthcoming meeting (24 March) of the Working Group and reviewed by external reviewers before presentation to the GMO Panel.

**Self-tasking on Statistics**

The Panel was informed that the final report of the statistics Working Group is ready and it will be presented for adoption at the next plenary meeting. The Panel expressed its gratitude to the Chair of the Working Group, Hilko Van der Voet, and all the experts who contributed to the development of the report.

**GM animals**

The Panel was updated on the progress of the work on GM animals, especially on the successful call for tender on GM fish and the draft status of the calls for tender on GM insects and GM birds. These calls will provide basis for guidance on environmental risk assessment of GM animals. For developing guidance on risk assessment of food/feed safety aspects of GM animals, a Working Group on GM animals has been implemented. The Working Group on GM animals met in February to develop a working strategy that includes the preparation of an inventory of existing guidance and other relevant documents as well as collecting technical background information related to the topic as the basis for drafting the guidelines.

## 10. ANY OTHER BUSINESS

**Collaboration with JRC**

The Panel discussed possible strategies for further collaboration with the JRC, as it was discussed by the food/feed Panel experts and JRC scientists during a dedicated meeting in December 2008. In particular possible flow and exchange of information between JRC and EFSA was discussed and encouraged for the future on a case-by-case basis, in the frame of the distinct responsibilities that EFSA and the JRC have with respect to EU legal requirements.

**Feedback of the meetings with applicants**

The Panel was informed about the topics discussed between the GMO unit and the applicants at the technical meeting of 3 March 2009. The meeting aimed to discuss applications, recurrent questions from the GMO Panel and procedural issues. The meeting resulted in a fruitful discussion.

**EC colleagues as observers during WG meetings**

As standard procedure EC colleagues are invited to all meetings of the GMO Panel and all its Working Group meetings. Six contact persons from DG SANCO and DGENV were reconfirmed.