



European Food Safety Authority

MINUTES OF THE 7TH PLENARY MEETING OF THE SCIENTIFIC PANEL ON GENETICALLY MODIFIED ORGANISMS HELD ON 10 AND 11 FEBRUARY 2004 (ADOPTED ON 3 MARCH 2004)

AGENDA

1.	WELCOME AND APOLOGIES FOR ABSENCE	2
2.	ADOPTION OF THE AGENDA	2
3.	DECLARATION OF INTERESTS.....	2
4.	ADOPTION OF THE MINUTES OF THE 6 TH PLENARY MEETING HELD ON 20-21 JANUARY 2004	2
5.	DISCUSSION AND POSSIBLE ADOPTION OF OPINIONS ON:	2
5.1.	SELF TASKING ACTIVITY ON ANTIBIOTIC RESISTANCE MARKERS	2
5.2.	QUESTION FROM THE COMMISSION ON GM OILSEED RAPE GT73 (APPLICATION UNDER 2001/18)	2
5.3.	2 QUESTIONS FROM THE COMMISSION ON GM MAIZE MON863, MON863xMON810 (APPLICATION UNDER 258/97 AND 2001/18)	3
6.	PROGRESS REPORT ON:	4
6.1.	QUESTION FROM COMMISSION REGARDING GUIDANCE FOR GM FOOD AND FEED APPLICATIONS UNDER REGULATION (EC) 1829/2003	4
6.2.	UPDATE OF TERMS OF REFERENCE FOR SELF TASKING ACTIVITIES	4
7.	NEW REQUESTS TO GMO PANEL: UPDATE DRAFT WORK PROGRAM – PRESENTATION AND DISCUSSION OF MANDATES	4
8.	APPOINTMENT OF RAPPORTEURS FOR NEW QUESTIONS	4
9.	ANY OTHER BUSINESS	4

PARTICIPANTS

GMO Panel:

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EFSA:

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

European Commission:

Sylvie Mestdagh¹ (DG ENV), Michael Walsh (DG SANCO D5 – Interface unit)

APOLOGIES

GMO Panel:

Marc De Loose, Colin Hill, Niels Hendriksen, Fergal O’Gara (Vice-Chair) and Angela Sessitsch

¹ Present on 10 January.

1. WELCOME AND APOLOGIES FOR ABSENCE

The Chairman opened the meeting and welcomed all. Apologies for absence were received from some experts as mentioned above.

2. ADOPTION OF THE AGENDA

The agenda was adopted as proposed.

3. DECLARATION OF INTERESTS

Declarations of interests with regard to oilseed rape GT73 and GM maize MON863, MON863xMON810 applications were noted during the 5th Plenary meeting.

No interests were declared for the other agenda items.

4. ADOPTION OF THE MINUTES OF THE 6TH PLENARY MEETING HELD ON 20-21 JANUARY 2004

The minutes of the 6th plenary meeting (20-21 January 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/pdf/gmo/minutes_gmo_06_adopied_en.pdf.

5. DISCUSSION AND POSSIBLE ADOPTION OF OPINIONS ON:

5.1. Self tasking activity on antibiotic resistance markers

A revised document 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. There was an exchange of views on the proposed classification of antibiotic resistance marker genes on the basis of their distribution and of the present state of therapeutic importance of relevant antibiotics. The experts agreed in principle with the proposed layout for the opinion and suggestions for modification were made. Finalisation of the document is foreseen by next plenary meeting.

5.2. Question from the Commission on GM oilseed rape GT73 (application under 2001/18)

Introduction

The GMO Panel was tasked to provide a risk assessment of GT73 oilseed rape, genetically modified to provide tolerance to the herbicide glyphosate. The risk assessment is based on a request by the Commission for a scientific opinion on GM oilseed rape GT73 (notification C/NL/98/11) introduced under Directive 2001/18/EC (EFSA-Q-2003-078). The scope of this application is import, processing and feed use.

The GMO Panel set up 3 working groups (WG) to examine the application: one WG dealt with the molecular characterisation of the GMO, one WG dealt with food and feed issues (comparative analysis, toxicology and allergenicity) and the third WG studied the environmental aspects related to the proposed uses of the GM oilseed rape.

In its evaluation the Panel focused in particular on the issues that were raised by Member States during their initial assessment of the application introduced under 2001/18/EC. The assessment is based on the information provided in the application including additional information from the applicant in reply to questions from Member States and from EFSA.

Discussion

The draft opinion was presented to the Panel members during the plenary meeting. Although all members agreed on the overall content of the opinion, some editorial changes and suggestions for clarification were discussed.

As a main conclusion the opinion states that:

The EFSA GMO Panel considered the information made available by the applicant as sufficient to assess the safety of GT73 oilseed rape and to address all the specific questions raised by the Member States related to risk assessment. Therefore additional experimental studies are not deemed necessary.

GT73 oilseed rape has been developed for tolerance to glyphosate herbicide by the introduction of a glyphosate-tolerant 5-enolpyruvylshikimate-3-phosphate synthase gene (*epsps*) from *Agrobacterium* sp., and a glyphosate-degrading glyphosate oxidoreductase gene (*gox*) from *Ochrobacter anthropi*. The GMO Panel has considered information provided on (1) the molecular inserts within the transgenic event, (2) the chemical composition of the GM and non-GM oilseed rape, (3) the safety of the proteins expressed and (4) the potential for risks associated with any changes to the toxicological, allergenic or nutritional properties of GT73 oilseed rape. Having considered the evidence, the GMO Panel is of the opinion that GT73 oilseed rape is as safe as conventional oilseed rape for humans and animals, and, in the context of its proposed use, the environment.

Adoption

The opinion was adopted by the Panel by consensus. There were no minority opinions. The opinion will be published on the EFSA website at: http://www.efsa.eu.int/p_gmo_en.html.

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

The rapporteurs of the three working groups for the evaluation of GM maize MON863, MON863xMON810 (Molecular Characterisation, Food/Feed Safety and Environmental Risk Assessment) presented the outcome of the respective working group meetings. Additional to the questions raised during the 5th plenary meeting, the Panel identified some further questions for clarification to be sent to the applicant. This request for additional information may cause a further delay in the adoption of the final EFSA opinions on these applications.

6. PROGRESS REPORT ON:

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

The rapporteur reported on the progress made since the last meeting of the GM food and feed guidance working group held on 29 January 2004. Although it was agreed earlier that the guidance document on GM crops and derived food and feed will be of first priority, also the guidance document on GMM should be dealt with urgently. With regard to GMO-derived additives, the discussions could start along with the elaboration of the guidance document on GMM. A sub-group was set up to establish a guidance document for genetically modified micro-organisms (GMM) and derived food and feed; this WG held its first meeting on 6 February 2004.

The Panel expressed concerns on the fact that the mandate for establishing these guidance documents is still unclear, in particular whether highly purified products produced with GMOs fall within the remit of the GMO Panel. It would for instance be more logical that the GMO Panel focuses its assessment on the genetic modification itself and that for the remainder of the safety assessment of highly purified products reference is made to existing guidelines. The Commission will be contacted for clarification of these issues.

6.2. Update of terms of reference for self tasking activities

The terms of reference of the self tasking activity on “Post Market Environmental Monitoring” was adapted to clarify the mandate. The amended mandate for this activity, approved by the GMO Panel, will be submitted to the Executive Director.

The mandate of the self tasking activity on “Impact of GMOs on microbial biodiversity and function in the soil environment” was redrafted by the rapporteur, as was discussed during the 6th Plenary meeting of 20 and 21 January 2004. The amended mandate will be submitted to the Executive Director.

7. NEW REQUESTS TO GMO PANEL: UPDATE DRAFT WORK PROGRAM – PRESENTATION AND DISCUSSION OF MANDATES

EFSA received from the Commission an advance copy for two new requests for a scientific opinion on GM maize 1507 (notification C/NL/00/10) and on GM maize Bt 11 (notification C/F/96/05.10), both introduced under Directive 2001/18/EC. The formal requests for opinion and accompanying documentation can be expected by the end of February 2004.

8. APPOINTMENT OF RAPPORTEURS FOR NEW QUESTIONS

Rapporteurs have been appointed for the new questions as mentioned under item 7.

9. ANY OTHER BUSINESS

There were no items discussed.