



European Food Safety Authority

MINUTES OF THE 10TH PLENARY MEETING OF THE SCIENTIFIC PANEL ON GENETICALLY MODIFIED ORGANISMS HELD ON 22 APRIL 2004 (ADOPTED ON 26 MAY 2004)

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PARTICIPANTS

GMO Panel:

Hans Christer Andersson, Detlef Bartsch, Howard Davies, Colin Hill, Marc De Loose, Michael Gasson, Niels Hendriksen, Sirpa Kärenlampi, Ilona Kryspin-Sorensen, Harry Kuiper (Chair), Marco Nuti, Fergal O'Gara (Vice-Chair), Pere Puigdomenech Rosell, George Sakellaris, Joachim Schiemann, Willem Seinen, Angela Sessitsch and Jeremy Sweet (Vice-Chair)

EFSA:

Suzy Renckens (scientific co-ordinator GMO Panel), Geoffrey Podger¹ (Executive Director), Ellen Van Haver (assistant scientific co-ordination GMO Panel)

European Commission:

Andreas Klepsch² (DG SANCO) and Michael Walsh³ (DG SANCO D5 – Interface unit)

¹ Only present for agenda item 9.

APOLOGIES

GMO Panel:

Hans-Joerg Buhk, Jan Dirk Van Elsas and Jean-Michel Wal

1. WELCOME AND APOLOGIES FOR ABSENCE

The Chairman opened the meeting and welcomed all. Apologies for absence were received from Hans-Joerg Buhk, Jan Dirk Van Elsas and Jean-Michel Wal.

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. Several members indicated that they were to some extent involved in the safety assessment process of the GMO applications (agenda items 5.1 and 5.2) at national level^{4&5} and will provide 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 the applications dossiers by EFSA.

4. ADOPTION OF THE MINUTES OF THE 9TH PLENARY MEETING HELD ON 2 APRIL 2004

The minutes of the 9th plenary meeting (2 April 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/49_en.html

5. DISCUSSION AND POSSIBLE ADOPTION OF OPINIONS ON:

5.1. Question from Commission regarding GM maize Bt11 (application under 2001/18)

EFSA has received from the Commission a request for a scientific opinion relating to an application for the placing on the market of Bt11 maize (C/F/96/05.10) introduced within the framework of

² Attending afternoon session only.

³ Attending morning session only.

⁴ Bt11 maize: Declarations were made by Hans Christer Andersson, Detlef Bartsch, Hans-Joerg Buhk, Marc De Loose, Colin Hill, Sirpa Kärenlampi, Harry Kuiper and Joachim Schiemann.

⁵ 1507 Maize: Declarations were made by Hans Christer Andersson, Detlef Bartsch, Hans-Joerg Buhk, Michael Gasson, Colin Hill, Sirpa Kärenlampi, Harry Kuiper and Joachim Schiemann.

Directive 2001/18/EC (question EFSA-Q-2004-012). Bt11 maize has been genetically modified to provide resistance to Lepidopteran insects. The scope of the application covers import, feed and industrial processing and cultivation of the maize.

On 21 April 2004 the application was discussed in the three working groups (Molecular Characterisation, Food/Feed Safety and Environmental Risk Assessment). The coordinators of the working groups presented the outcome of this meeting. The GMO Panel identified some issues that need to be further clarified/documentated by the applicant or by the Commission.

5.2. Question from Commission regarding GM maize 1507 (application under 2001/18)

EFSA has received from the Commission a request for a scientific opinion relating to an application for the placing on the market of 1507 maize (C/NL/00/10) introduced within the framework of Directive 2001/18/EC (question EFSA-Q-2004-011). 1507 Maize is genetically modified for insect resistance to Lepidopteran insects and herbicide tolerance to glufosinate ammonium. A first discussion on the dossier was held on 21 April 2004.

5.3. Question from Commission regarding guidance for GM food and feed applications under Regulation (EC) 1829/2003: guidance document on GM food/feed containing GMM

An updated version of the guidance document of genetically modified micro-organisms (GMM) was distributed during the meeting. The Panel discussed the draft guidance document and identified some action items for the next meeting.

5.4. Question from Commission regarding guidance for GM food and feed applications under Regulation (EC) 1829/2003: guidance document on food/feed substances produced from/with GMOs

A working group has been set up to establish a guidance document on GMO derived substances. On 1 April 2004, a first 'brainstorming' meeting took place to clarify the different categories of products that could fall within the scope of this guidance. Moreover, as these products could also be regulated by other legislations and therefore fall within the remit of other EFSA Panels, the interplay with these Panels was identified. The WG decided that further clarifications would be needed from the Commission with regard to substances derived from GMOs that are produced in a contained environment, in accordance with Directive 90/219/EEC, as amended by Directive 98/81/EC: the question was raised whether such substances also fall within the scope of Regulation (EC) 1829/2003.

6. PREPARATION STAKEHOLDER CONSULTATION 25 MAY 2004

EFSA and the GMO Panel will organise a stakeholder consultation meeting on 25 May 2004 to discuss the "Draft guidance document on genetically modified plants and derived food and feed". This draft guidance was published on the EFSA website (http://www.efsa.eu.int/consultation/372_en.html) on 7 April 2004 and interested parties were invited to submit written comments through an on-line consultation process. The GMO Panel will consider the comments and discuss them with the stakeholders at the consultation of 25 May prior to the finalisation of the document.

7. START SELF TASKING ACTIVITY POST MARKET ENVIRONMENTAL MONITORING

A letter from the Executive Director of EFSA was distributed to the Panel members with his approval to start the self tasking activity on post market environmental monitoring (PMEM). The Panel identified the members and *ad hoc* experts that could participate in the PMEM working group. A first working group meeting was scheduled for 12 May 2004.

8. DATE AND PLACE OF FUTURE MEETINGS

The Plenary meeting of July will be held in Barcelona. Some dates for working group meetings were proposed.

9. ANY OTHER BUSINESS

The Executive Director of EFSA informed the Panel about the EFSA decision to request from the applicant Monsanto a 90-day study for the hybrid maize MON 863 x MON 810 after the adoption of the opinions on genetically modified maize MON 863 and the maize hybrid MON 863 x MON 810^{6&7}. In these opinions, the Panel concluded that MON 863 maize is as safe as conventional maize. With regard to the hybrid MON 863 x MON 810, the Panel however could not reach a conclusion as it was divided over the need for confirmatory data for the safety assessment of the hybrid, in particular, the need for an additional 90-day rat study with MON 863 x MON 810.

The Panel was informed by the Commission representative about a new request from the Commission for an opinion of the GMO Panel. This request regards additional information submitted by Austria and Greece in the context of existing 'safeguard clauses' invoked under Article 16 of Directive 90/220/EEC: transmission of documents to the European Food Safety Authority requesting a scientific opinion. At the time of the meeting, the EFSA GMO secretariat had not yet received this request.

A copy of a letter from the Commission, including a letter from the German authorities with information on the evaluation of GMOs used as feed, was distributed to the Panel members. This information has been considered by the GMO Panel within the framework of the draft guidance document on GM plants and derived food and feed.

The Panel received an update of the applications introduced under part C, 2001/18/EC- (Deliberate releases and placing on the EU market of GMOs⁸) that are currently being assessed by Member States. In the case there will be objections from Member States, these notifications will be forwarded to EFSA for a scientific opinion of the GMO Panel.

⁶ Opinion of the Scientific Panel on Genetically Modified Organisms on a request from the Commission related to the safety of foods and food ingredients derived from insect-protected genetically modified maize MON 863 and MON 863 x MON 810, for which a request for placing on the market was submitted under Article 4 of the Novel Food Regulation (EC) No 258/97 by Monsanto, The EFSA Journal (2004) 50, 1-25

⁷ Opinion of the Scientific Panel on Genetically Modified Organisms on a request from the Commission related to the Notification (Reference C/DE/02/9) for the placing on the market of insect-protected genetically modified maize MON 863 and MON 863 x MON 810, for import and processing, under Part C of Directive 2001/18/EC from Monsanto, The EFSA Journal (2004) 49, 1-25

⁸ <http://gmoinfo.jrc.it/gmc Browse.asp>

A copy of the EFSA Code of Conduct on Declarations of Interests was distributed to the Panel members for information. Members were asked to provide their comments to the EFSA GMO secretariat prior to the final approval of the document.
