European Food Safety Authority

# MINUTES OF THE 6TH PLENARY MEETING OF THE SCIENTIFIC PANEL ON GENETICALLY MODIFIED ORGANISMS HELD ON 20 AND 21 JANUARY 2004 (ADOPTED ON 10 FEBRUARY 2004)

## AGENDA



## PARTICIPANTS

*GMO Panel:*
Hans Christer Andersson, Detlef Bartsch, Hans-Joerg Buhk[1], Howard Davies, 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[1], George Sakellaris, Joachim Schiemann, Willem Seinen, Angela Sessitsch, Jeremy Sweet (Vice-Chair) and Jean-Michel Wal

*EFSA:*
Herman Koëter[2] (Deputy Executive Director and Head of Science), Suzy Renckens (scientific co-ordinator GMO Panel), Ellen Van Haver (assistant scientific co-ordination GMO Panel)

*European Commission:*
Andreas Klepsch[1] (DG SANCO), Sylvie Mestdagh[3] (DG ENV), Michael Walsh (DG SANCO D5 – Interface unit)

[1] Present on 21 January.

[2] Present for agenda item 11

**APOLOGIES**

*GMO Panel:*
Colin Hill, Jan Dirk Van Elsas

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## 1. WELCOME AND APOLOGIES FOR ABSENCE

The Chairman opened the meeting and welcomed all. Apologies for absence were received from Colin Hill and Jan Dirk Van Elsas.

## 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 5TH PLENARY MEETING HELD ON 11 DECEMBER 2003

The minutes of the 5th plenary meeting (11 December 2003) 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_05_adopted_en.pdf.

## 5. FEEDBACK FROM THE SCIENTIFIC COMMITTEE

The Chair gave an overview of the outcome of the 5th Plenary meeting of the EFSA Scientific Committee held on 15 January 2004. The minutes of this meeting are published at: http://www.efsa.eu.int/pdf/minutes_sci_05_adopted_en.pdf.

In relation to the move of EFSA to Parma, Panel members are concerned about the organisation of future meetings, because of the difficult accessibility to Parma which will increase travelling times. It was indicated that there would be a need for flexibility whereby meetings, especially those of working groups, could also be organised at more central locations.

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[3] Present on 20 January.

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

### 6.1. Self tasking activity on antibiotic resistance markers

As no further progress was made on the draft opinion on antibiotic resistance markers, the possible adoption of an opinion was referred to a later date. The rapporteur indicated that there was a common understanding in the working group on the contents of the opinion and that the remaining work to be done consists of the final wording and structuring of the opinion. A document will be distributed before next plenary meeting.

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

EFSA received from the Commission, a request 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.

At the last plenary meeting the Panel decided to raise questions to the applicant for clarification. The applicant has provided answers to these questions, which were transmitted through the Dutch Competent Authority, the lead Member State for this application. These answers were considered by the respective working groups.

The GMO Panel is however not fully satisfied with the responses received from the applicant and it was therefore decided that EFSA will approach the applicant again with the request of providing further additional information. This implicates however that the stop-the-clock mechanism should apply while EFSA is awaiting further information. EFSA has sent a letter to the Commission (DG Environment) to inform the Commission about this procedure.

## 7. ADOPTION OF TERMS OF REFERENCE FOR SELF TASKING ACTIVITIES AND PRIORITY SETTING

The following proposals for self tasking activities were discussed in order of priority. The timeframe and possible experts were indicated for each topic.

- Post market environmental monitoring of crops

  This self tasking activity was considered as of high priority in view of the forthcoming applications for cultivation of GM crops, for which monitoring plans proposed by the applicants have to be assessed, and in view of establishing guidance for GM food and feed applications (see point 8.2). As this issue is strongly related to management practices, it is recommended to establish an interface with the Commission and the Competent Authorities from the Member States. The mandate for this activity, approved by the GMO Panel, will be submitted to the Executive Director.

- Assessment of allergenicity of genetically modified (GM) foods

  This self tasking activity is aimed at discussing and assessing strategies and methods currently used, identifying shortcomings and making proposals for improvement of the methodology. This could include the development of a new paradigm and more accurate and sensitive tests as to increase the level of 'non-allergenicity' of GM crops/foods, particularly with regard to the

evaluation of future generations of GMOs. As research might be needed in this area, the outcome of the discussion will be communicated to DG research and, vice versa, the outcomes of ongoing research projects will be taken into account during this activity. It was agreed that the rapporteur will redraft the mandate and indicate the estimated work and timeframe for this activity before submitting it to the Executive Director.

- Impact of GMOs on microbial biodiversity and function in the soil environment

  This self tasking activity will be established in 2 steps: the aim of the first step is to work out this issue in general terms in view of the guidance document for GM food and feed applications (see point 8.2); the second step is aimed at providing more detailed guidance on this subject. It was agreed that the rapporteur will redraft the mandate and indicate the estimated work and timeframe for this activity before submitting it to the Executive Director.

- Post market surveillance of genetically modified (GM) foods

  As this is a very complex issue, which is not solely related to GMOs, it was suggested to discuss this issue within the Scientific Committee.

- Safety of use of viral promoters and specifically of the cauliflower mosaic virus (CaMV) promoter

  This self tasking activity is deferred to a later stage.

## 8. PROGRESS REPORT ON:

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

The GMO panel had formulated some questions for clarification to the applicant during the 5th plenary meeting and has received an answer from the applicant, through the German Competent Authority. The application will be further considered by the three working groups (Molecular Characterisation, Food/Feed Safety and Environmental Risk Assessment).

### 8.2. 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 16 December 2003.

The Panel members agreed with the proposed calendar for this activity. A draft guidance document for applications of GM food and feed derived from GM crops will be finalised by April 2004 and published on the EFSA website. There will be an opportunity for the public to make written comments and the process will be concluded by a stakeholder consultation in May 2004.

The Panel members discussed the interplay between Regulation 1829/2003 and Directive 2001/18/EC and agreed that EFSA should ask the Commission to provide more guidance on this issue.

## 9. OUTLINE AND ORGANISATION OF STAKEHOLDER CONSULTATION ON GM FOOD AND FEED GUIDANCE

The Panel members had a discussion on the content as well as some organisational issues in relation to the stakeholder consultation that is scheduled for 25 May 2004.

## 10. UPDATE DRAFT WORK PROGRAM

EFSA has received no new requests for scientific opinion since the last plenary meeting.

The Panel members were informed that the Commission has decided not to consult EFSA on the issue of thresholds for GM seeds in conventional seed lots, that was discussed at the last plenary meeting.

The scientific coordinator informed the Panel of potential upcoming requests relating to authorisation dossiers introduced under Directive 2001/18/EC.

## 11. ANY OTHER BUSINESS

The Panel was informed about the case of dead cows in Germany fed silage from Bt 176 maize. The Robert Koch Institute (RKI) in Berlin led an investigation and asked several experts from public and private research institutions for their opinion on this case. The RKI concluded that a causal relationship between the feed containing Bt toxin from Bt 176 maize and the deaths is extremely unlikely. The cause of these problems is more likely to have been an accumulation of factors including surplus of protein, high infectious pressure, feeding with grass silage of questionable quality and most of all insufficient or even inexistent 'transition' between different feeding regimes (quantitatively not adapted to needs). Furthermore, poor hygiene conditions were noted on the farm. Further information can be found at http://www.biosicherheit.de/aktuell/248.doku.html.

At the last plenary meeting the Panel was informed about a letter raising the issue of the possibility of instability of transgenes in some genetically modified plants. The issue was discussed and will be further considered in the future.

The Deputy Executive Director and Head of Science of EFSA informed the Panel of the future structure of the science department of EFSA. Additional to the Scientific Committee and Expert Panels division, a division of scientific expert services will be created to assist the Panels in performing preparatory work. This new division will be composed of experts with expertise in different areas, such as toxicology, exposure assessment and epidemiology, environmental effect assessment etc.