European Food Safety Authority

MINUTES OF THE 5TH PLENARY MEETING OF THE SCIENTIFIC PANEL ON GENETICALLY MODIFIED ORGANISMS HELD ON 11 DECEMBER 2003

AGENDA

PARTICIPANTS

GMO Panel:

Hans Christer Andersson, Detlef Bartsch, Hans-Joerg Buhk, Howard Davies, Marc De Loose, Michael Gasson, Niels Hendriksen, Colin Hill, Sirpa Kärenlampi, Ilona Kryspin-Sorensen, Harry Kuiper (Chair), Marco Nuti, Pere Puigdomenech Rosell, George Sakellaris, Joachim Schiemann,

Willem Seinen, Angela Sessitsch, Jeremy Sweet (Vice-Chair), Jan Dirk Van Elsas and Jean-Michel Wal[1]

EFSA:
Susan Parker (administrative secretary GMO Panel), Suzy Renckens (scientific co-ordinator GMO Panel), Ellen Van Haver (assistant scientific co-ordination GMO Panel)

European Commission:
Hervé Martin[2] (DG ENV), Sylvie Mestdagh (DG ENV), Guy Van den Eede[3] (DG JRC), Michael Walsh (DG SANCO D5 – Interface unit)

APOLOGIES

GMO Panel:
Fergal O'Gara (Vice-Chair)

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1. WELCOME AND APOLOGIES FOR ABSENCE

The Chairman opened the meeting and welcomed all. Apologies for absence were received from Fergal O'Gara.

2. ADOPTION OF THE AGENDA

The agenda was adopted as proposed.

3. DATES FOR PLENARY MEETINGS IN 2004

In addition to the dates proposed at the 3rd Plenary Meeting (see the minutes of the meeting at: http://www.efsa.eu.int/pdf/minutes_gmo_03_adopted_en.pdf), the following dates have been proposed for plenary meetings in 2004: 10 – 11 February 2004, 23 – 24 September 2004, 9 – 10 November 2004, 8 – 9 December 2004.

4. 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 9.2 and 9.3) at national level[4][5]. It was decided from these

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[1] Attending morning session only.

[2] Present for agenda item 14.

[3] Present for agenda item 11.

[4] Oilseed rape GT73 : Declarations were made by Detlef Bartsch, Hans-Joerg Buhk, Marc De Loose, Harry Kuiper, Joachim Schiemann and Jeremy Sweet.

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. Members that are directly involved in the risk management process of GMO authorisations in their country, can contribute to the scientific discussions but will not take part in the final adoption of the opinion.

5. ADOPTION OF THE MINUTES OF THE 4TH PLENARY MEETING HELD ON 25 NOVEMBER 2003

The minutes of the 4th plenary meeting (25 November 2003) were adopted. The minutes of this meeting are published at: http://www.efsa.eu.int/pdf/gmo/minutes_gmo_04_adopted_en.pdf.

6. FEEDBACK FROM THE SCIENTIFIC COMMITTEE

The Vice-Chair gave an overview of the outcome of the 4th Plenary meeting of the EFSA Scientific Committee held on 19 and 20 November 2003. The minutes of this meeting are published at: http://www.efsa.eu.int/pdf/minutes_sci_04_adopted_en.pdf.

A copy of the "Media handling guidelines for the Scientific Committee and the Panels" was distributed among the members. Members were invited to send their comments to EFSA.

7. FEEDBACK FROM EFSA

The Chair gave some feedback on the press-conference organised by EFSA on GM maize NK603, held on 4 December 2003. Documents of the press release can be found at: http://www.efsa.eu.int/pdf/pressrel_gmo_0203_final_en.pdf.

The members discussed the possible involvement of stakeholders in the future work of the GMO panel (see also item 9.1).

8. DISCUSSION AND POSSIBLE ADOPTION OF OPINIONS ON:

8.1. Question from the Commission regarding GMM guidelines for contained use

Introduction

EFSA received a request (EFSA-Q-2003-004) to provide a scientific opinion on the draft Annex "Guidance notes supplementing Part B of Annex II to Directive 90/219/EEC on the contained use of genetically modified micro-organisms" (see the minutes of the third plenary meeting: http://www.efsa.eu.int/pdf/minutes_gmo_03_adopted_en.pdf). EFSA was requested to focus particularly on any new scientific knowledge or developments that may have arisen since the Scientific Committee on Plants issued its opinion in 1999.

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[5] GM maize MON863, MON863xMON810 : Declarations were noted from Hans Christer Andersson, Detlef Bartsch, Hans-Joerg Buhk, Sirpa Kärenlampi, Harry Kuiper, Joachim Schiemann and Jeremy Sweet.

Discussion

A working group was set up to deal with this specific request. A draft opinion was distributed to the Panel members. Annotated changes were made to the draft guidance notes. Although all members agreed on the overall content of the opinion, some editorial changes were made.

In the opinion the following conclusions and recommendations are made:

The GMO Panel supports the necessity of defining the criteria to be met when establishing the safety of individual types of GMMs for human health and the environment and endorses the need to produce robust guidance notes for the easy application of such defined and agreed criteria in a user-friendly manner. However, the GMO Panel recommends that it would be very beneficial if robust guidance notes were produced as soon as is practicable for the individual groups of key micro-organisms that fall within the scope of the Directive. Finally, the Panel has produced a modified annotated draft of the guidance notes outlining all the modifications suggested by the Panel.

Adoption

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

8.2. Self tasking activity on antibiotic resistance markers

The co-ordinator of the working group on 'antibiotic resistance marker genes' gave an overview of the outcome of the working group meeting held on 26 November 2003. A possible adoption of the opinion on antibiotic resistance markers is foreseen during the next plenary meeting.

9. PROGRESS REPORTS ON:

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

The GMO panel set up a working group to establish guidance notes for applications introduced within the framework of the new GM food and feed Regulation (question EFSA-Q-2003-005). The group has already met once and a second meeting was scheduled for 16 December 2003. The progress made was reported to the Panel.

The members discussed ways of involving the public and stakeholders in this process. The GMO panel considered the possibility of organising a stakeholder consultation on the GM food and feed guidance document. A small working group will prepare an outline for such a consultation.

9.2. 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 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 to examine the molecular characterisation of the GMO, the feed issues (comparative analysis, toxicology and allergenicity) and the environmental aspects related to the proposed uses of the GM maize.

A draft opinion on the safety assessment of GT73 oilseed rape was distributed to the members. The co-ordinators of the three working groups (Molecular Characterisation, Food/Feed Safety and Environmental Risk Assessment) each gave an overview of the outcome of the working group meetings. The GMO panel formulated some questions to be sent to the applicant for clarification. The request for additional information from the applicant may delay the assessment process and, consequently, EFSA may not be able to finalise its opinion by the initially set deadline (end of January 2004). It was agreed that EFSA would approach the Commission for clarification of the issues relating to processes and timing of potential requests from the GMO Panel for additional information for applications introduced within the framework of Directive 2001/18/EC.

9.3. 2 Questions from the Commission on GM maize MON863, MON863xMON810 (application under 258/97 and 2001/18)

EFSA received, from the Commission, two requests for a scientific opinion on GM maize MON863 and MON863 X MON810 introduced under Directive 2001/18/EC (EFSA-Q-2003-108) and Regulation (EC) 258/97 (EFSA-Q-2003-121).

The co-ordinators of the three working groups (Molecular Characterisation, Food/Feed Safety and Environmental Risk Assessment) dealing with the evaluation of GM maize MON863, MON863xMON810 presented the outcome of the working group meetings. As some points of the application were unclear, the GMO panel agreed on questions to be sent to the applicant for clarification of some specific issues.

10. TERMS OF REFERENCE FOR SELF TASKING ACTIVITIES

The members of the GMO Panel are invited to provide written comments by the next plenary meeting on the following proposals for self tasking activities:

- Impact of GMOs on microbial biodiversity and function in the soil environment
- Post market monitoring of crops
- Assessment of allergenicity of genetically modified (GM) foods
- Post market surveillance of genetically modified (GM) foods
- Safety of use of viral promoters and specifically of the cauliflower mosaic virus (CaMV) promoter.

11. PRESENTATION BY DR. GUY VAN DEN EEDE ON THE ROLE OF THE JOINT RESEARCH CENTRE AND THE FUTURE COMMUNITY REFERENCE LABORATORY IN THE VALIDATION OF GMO DETECTION METHODS

Guy Van den Eede, Head of Unit "Biotechnology and GMOs" of the DG Joint Research Centre (JRC), gave a presentation on the technical and scientific support of the JRC to the implementation of the EU Biotechnology Regulations. The presentation was aimed at providing the GMO panel with more insight into the process of validation of detection methods. More information on the validation process of detection methods and on the role of the European Network of GMO labs (ENGL) can be found at: http://engl.jrc.it.

12. INFO ON UK FARM SCALE EVALUATIONS

Jeremy Sweet informed the GMO panel about the outcome of 'the farm scale evaluations (FSE) in the UK of spring sown genetically modified crops to assess the potential implications of large scale growing GM herbicide-tolerant crops on farmland biodiversity'. The findings of the FSE have been published in a special issue of the Philosophical Transactions of the Royal Society.

13. SUBMISSIONS TO THE GMO PANEL

EFSA received 2 submissions from organisations relating to the risk assessment of GMOs that were distributed to the Panel members. The first submission, entitled "The EFSA GM Food Safety Challenge" was made by Friends of the Earth and GeneWatch UK, the second submission, consisting of two comments on "Transgenic instability", were received from the Institute of Science in Society (ISIS) in the UK. The submissions were considered and discussed by the members of the GMO Panel.

With regard to the second submission on transgenic instability, a report referred to data published by two national institutes: the Service of Biosafety and Biotechnology (SBB) of the Scientific Institute of Public Health in Belgium and the "Laboratoire de Méthodologies de la Détection des OGM de l'Institut National de la Recherche Agronomique de Versailles" in France.

Both institutes have been contacted by EFSA for clarification of the data in their reports with regard to the instability of GM crops. EFSA received an answer from the Belgian Service of Biosafety and Biotechnology. In 1999, a laboratory of the Belgian Competent Authority (Agricultural Research Centre, Melle) found that the genomic mapping of GTS-40-3-2 soybean from Monsanto was inconsistent with the data provided in the original dossier. As a consequence, the same laboratory was asked by the Belgian Government in charge of Directive 90/220/EEC and Regulation (EC) 258/97 to re-evaluate the molecular data of 6 other commercial GMOs. The report, published by the SBB, 'contains the data of this re-evaluation and does not regard it a priority to interpret this data in terms of safety for human health and the environment, but in terms of control (detection methods) by the member states'. EFSA was informed that the Belgian report will be submitted to the European Commission.

EFSA will undertake further actions to clarify the issue.

14. ANY OTHER BUSINESS

Hervé Martin of the European Commission (DG Environment) explained the purpose of his presence at the GMO plenary meeting. In 2000, the former Scientific Committee on Plants (SCP) was asked to deliver an opinion on proposed thresholds for GM seeds in conventional seed lots that would allow the 1% threshold (below which the adventitious presence of GMOs in food and feed products does not need to be labelled as containing GMOs) to be met. The proposed threshold values were 0.3% for cross-pollinating crop species and 0.5% for self-pollinating crops species. The SCP delivered its opinion in 2001 (http://europe.eu.int/comm/food/fs/sc/scp/out93_gmo_en.pdf) and confirmed it in January 2003 (http://europa.eu.int/comm/food/fs/sc/scp/out146_en.pdf).

The Commission is currently examining whether, considering the new threshold of 0.9% instead of 1% defined in the new Regulation (EC) 1829/2003 on GM food and feed, a question would be raised with EFSA to reconsider the threshold levels for GM seeds in view of new scientific evidence. Furthermore, DG Environment intends to propose more specific threshold levels on a per species basis. The GMO Panel was asked to give feedback on this type of request, as well as to give an idea of the timeframe necessary to deliver such an opinion. Because of the high workload of the GMO panel, the timeframe of 1 – 1.5 months as proposed by DG ENV, was not considered feasible. Furthermore, as this possible request rather concerns a management issue, which is not within the remit of EFSA, the status of such a request will need to be discussed further with the Executive Director of EFSA. Mr. Martin stressed that there was no formal decision by the Commission on this issue.