MINUTES OF THE 26TH PLENARY MEETING OF THE SCIENTIFIC PANEL ON GENETICALLY MODIFIED ORGANISMS HELD ON 16-17 MAY 2006 (ADOPTED BY WRITTEN PROCEDURE ON 16 JUNE 2006)

AGENDA

PARTICIPANTS

GMO Panel:
Hans Christer Andersson, Detlef Bartsch, Hans-Joerg Buhk, Howard Davies, Niels Bohse Hendriksen, Sirpa Kärenlampi, Ilona Kryspin-Sorensen, Harry Kuiper (Chair), George Sakellaris, Willem Seinen, Angela Sessitsch, Jeremy Sweet (Vice-Chair), Jan Dick Van Elsas and Jean-Michel Wal.

EFSA:
David Carlander (scientific officer, team GMO), Dirk Detken[1] (legal affairs), Anne_Laure Gassin[2] (Director of Communications), Karine Lheureux (scientific officer, team GMO), Luisa Mannu (scientific officer, team GMO), Sylvie Mestdagh (scientific officer, team GMO), Claudia Paoletti (scientific officer, team GMO), Suzy Renckens (scientific co-ordinator GMO Panel), Reinhilde Schoonjans (scientific officer, team GMO), Ellen Van Haver (assistant scientific co-ordinator GMO Panel).

European Commission:
Aurelie André (DG ENV), Dorothée André (DG SANCO), Sébastien Goux (DG SANCO), Paula Rey Garcia (DG ENV), Michael Walsh (DG SANCO).

APOLOGIES

GMO Panel:
Mike Gasson, Marc De Loose, John Heritage, Marco Nuti, Fergal O'Gara (Vice-Chair), Pere Puigdomenech and Joachim Schiemann.

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1. WELCOME AND APOLOGIES FOR ABSENCE

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

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. Declarations of interests with regard to applications already announced during previous Plenary meetings are noted in the corresponding minutes. There were no new applications on the agenda of this meeting.

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[1] Only present for agenda item 9.2.
[2] Only present for agenda item 8.

4. ADOPTION OF THE MINUTES OF THE 25TH PLENARY MEETING HELD ON 28-29 MARCH 2006

The minutes of the 25th plenary meeting (28-29 March 2006) were adopted as proposed. The minutes of this meeting are published at:

http://www.efsa.eu.int/science/gmo/gmo_meetings/1424_en.html

5. FEEDBACK FROM EFSA AND THE SCIENTIFIC COMMITTEE

The Panel was informed about the outcome of the 18th Plenary meeting of the Scientific Committee held on 10-11 April 2006. The minutes of this meeting are published at:

http://www.efsa.eu.int/science/sc_commitee/sc_meetings/1432_en.html

6. FEEDBACK FROM THE COMMISSION

The Panel was informed about a letter that EFSA received from the Commission following the Commission orientation debate of 12 April. In this letter, the Commission is pointing out that certain Member States have difficulty identifying their questions and the corresponding answers in certain opinions adopted by the Panel. The Commission therefore asks EFSA to provide more detailed justification in its opinions for the comments from the Member States for four specific applications (EFSA-GMO-UK-2004-01, EFSA-GMO-DE-2004-03, EFSA-GMO-UK-2004-06 and EFSA-GMO-BE-2004-07). However, at the technical meeting organised on 3 March by DG SANCO with the Member States, where EFSA presented the scientific opinions on these applications, no major concerns were expressed by the Member States. No specific comments were either raised by the Member States during the 30 days public consultation by DG SANCO (in accordance with articles 6&18(7) of Regulation (EC) N° 1829/2003), or during the EFSA GMO Forum of 15 May 2006 (see item 7). EFSA will therefore approach the Member States to identify which of the specific scientific comments are considered as not adequately addressed in the four scientific opinions and which would therefore trigger more detailed justification from the GMO Panel.

The Panel considered that it was not appropriate to reopen a detailed discussion on opinions which have already been adopted but that for future opinions efforts will be made to increase the transparency with respect to Member States views (see also item 7).

7. OUTCOME OF THE EFSA GMO FORUM WITH NATIONAL EXPERTS ON 15 MAY

EFSA convened a meeting between the GMO Panel and scientific representatives from the 25 EU Member States, Switzerland and Norway to discuss how to strengthen scientific co-operation in the risk assessment of GMOs (http://www.efsa.eu.int/science/gmo/catindex_en.html). EFSA and the chair of the GMO Panel gave a detailed overview of its present risk assessment and consultation process and discussed together with the delegates how the Member States could be better involved in the future.

A press release on this meeting has been published at: http://www.efsa.eu.int/press_room/press_release/1485_en.html.

The Panel discussed the outcome of the GMO Forum and was of the opinion that more regular meetings on focussed topics could strengthen the co-operation between EFSA and the Member States and could clarify aspects of the GMO risk assessment. The Panel also discussed ways to address more explicitly the comments from the Member States in future opinions on applications. A possible way would be to annex the comments from the Member States to the opinion and to indicate for each comment where it has been addressed in the opinion, or a justification why a specific comment was not addressed.

8. EFSA COMMUNICATIONS ACTIVITIES RELATED TO GMOS: LOOKING TOWARDS THE FUTURE

The EFSA Director of Communications gave a presentation on EFSA communications' activities related to GMOs and an overview of the media coverage on EFSA GMO issues.

Action items for the future EFSA communication strategy on GMOs were discussed with the Panel.

9. DISCUSSION AND POSSIBLE ADOPTION OF OPINIONS ON:

9.1. GM carnation Moonlite 123.2.38 (C/NL/04/02 under Directive 2001/18/EC)

Introduction

The GMO Panel was requested, under Article 29(1) and in accordance with Article 22(5)(c) of Regulation (EC) No 178/2002, to provide a scientific opinion as to whether there is any scientific reason to believe that the placing on the market of the GM Carnation Moonlite 123.2.38 for import of cut flowers for ornamental use is likely to cause any adverse effects on human health and the environment within the scope of Directive 2001/18/EC. In particular EFSA was requested to take account of the objections raised by competent authorities of Member States in this context.

Discussion

The assessment is based on the information provided in the application, including additional information from the applicant in reply to questions from Members States (MS) and from EFSA.

The draft opinion was presented to the Panel members during the plenary meeting followed by a discussion on outstanding issues.

The GMO Panel considered the potential impact of carnation Moonlite 123.2.38 in the very unlikely event that GM carnation petals would be consumed by humans or animals or accidentally released into the environment.

As a main conclusion, the opinion states that:

The Panel was asked to consider whether there is any scientific reason to believe that the placing on the market of the GM carnation Moonlite 123.2.38 for import is likely to cause any adverse effects on human health and the environment within the scope of Directive 2001/18/EC.
The carnation Moonlite 123.2.38 has a modified flower colour, a shade of violet, which is achieved by introducing into white carnation two genes of the anthocyanin biosynthesis pathway from petunia. Carnation Moonlite 123.2.38 also expresses sulfonylurea herbicide tolerance.

The Panel has evaluated the molecular analysis of the genetically modified variety. The carnation Moonlite 123.2.38 does not contain a functional antibiotic resistance marker gene. From the bioinformatic analysis, there is no reason to assume that the DNA regions transferred code for toxic and/or allergenic products.
Given the intended use of carnation Moonlite 123.2.38 (excluding human or animal consumption and cultivation), the Panel considers that the comparative analysis limited to the newly synthesised anthocyanins is sufficient for the risk assessment. Furthermore, based on the results of toxicity and allergenicity studies, there is no evidence that any of the three proteins expressed is toxic or allergenic. The Panel concludes that carnation Moonlite 123.2.38 is unlikely to have adverse effects on human or animal health in the unlikely event that carnation Moonlite 123.2.38 petals are consumed.
Considering the low environmental exposure due to the restricted scope of the notification, it is very unlikely that gene transfer and escape into the environment would occur due to the intended use of Moonlite 123.2.38 for cut flowers. In addition the impact of the three genes would be negligible for the environment. The Panel agrees with the general methods and approaches of the general surveillance plan provided in the notification.

Adoption

The opinion was adopted unanimously by the Panel. The opinion can be found on the EFSA website at:

http://www.efsa.eu.int/science/gmo/gmo_opinions/1559_en.html

9.2. Guidance document for the risk assessment of GMMs and derived food and feed

Introduction

In accordance with Articles 5(8) and 17(8) of Regulation (EC) N° 1829/2003 on genetically modified food and feed, EFSA has to publish detailed guidance to assist the applicant in the preparation and the presentation of the application for the authorisation of GM food and/or feed. EFSA has already published in November 2004 a first guidance document of the GMO Panel for the risk assessment of GM plants and derived food and feed (http://www.efsa.eu.int/science/gmo/gmo_guidance/660_en.html). The second guidance document prepared by the Panel provides detailed guidance for the risk assessment of genetically modified microorganisms (GMMs) and their derived products intended for food and feed use.

Discussion

The draft guidance document has been published for a period of 2.5 months (15 July to 30 September 2005) on the EFSA website for public consultation. The Panel has carefully considered all comments received during this consultation and agreed already on the scientific part of the revised draft guidance document at the 25th Plenary meeting (http://www.efsa.eu.int/science/gmo/gmo_meetings/1424_en.html). The remaining part of the document, dealing with the legal background, revised by EFSA and the Commission, was presented to the Panel for adoption.

Adoption

The guidance document was adopted unanimously by the Panel. The guidance document can be found on the EFSA website at:

http://www.efsa.europa.eu/science/gmo/gmo_guidance/1595_en.html

9.3. Natuphos – 3-Phytase

Introduction

Within the framework of Regulation (EC) N° 1831/2003, EFSA has been requested to deliver an opinion on whether the change of the producing strain (NPH54) and the change in concentration of the final product cause any modification to the safety or the efficacy of the enzyme preparation of 3-phytase (Natuphos®), produced using a genetically modified microorganism, when used under the proposed conditions.

Discussion

The GMO Panel has been asked to perform the assessment of the GM aspects of the microorganism used for the production of the feed enzyme. The FEEDAP Panel will assess all other parts of the application.

On the basis of the data submitted, the Panel concluded that it is unlikely that the genetic modification of *Aspergillus niger* NPH54 to produce 3-phytase will have any adverse effects on human and animal health or the environment.

Adoption

The opinion with regard to the risk assessment of the genetic modification of the application was adopted unanimously by the Panel. The opinion will be published on the EFSA website at:

http://www.efsa.eu.int/science/feedap/feedap_opinions/1568_en.html

10. NEW REQUESTS TO EFSA: DISCUSSION AND ADOPTION OF MANDATES

10.1. Safeguard clause invoked by Greece under article 18 of Directive 2002/53/EC and article 23 of Directive 2001/18/EC

EFSA received from the Commission a request, under Article 29(1) and in accordance with Article 22(5)(c) of Regulation (EC) No 178/2002, for a scientific opinion, as to whether:

- the scientific report and the scientific publications submitted by the Greek authorities show that there is an imminent danger for human health and the environment due to the cultivation of the maize varieties with the genetic modification MON 810.

EFSA does not need to consider specific elements contained in the introductory note of this document *e.g.* the fact that the decision of MON 810 was given in 1998 and should be renewed, discussions in the Council, reference to the Carthagena Protocol, reference to the Greek Constitution and to co-existence issues.

The Panel proposed to invite the Greek scientific experts who have written the scientific report underlying the request for this safeguard clause, to discuss with them their scientific concerns and

to identify whether there is new scientific evidence which was not considered in earlier risk assessments of the maize MON 810.

11. UPDATE ON APPLICATIONS RECEIVED UNDER DIRECTIVE 2001/18/EC, REGULATION (EC) 1829/2003 AND REGULATION (EC) 1831/2003

- 59122 maize (application EFSA-GMO-NL-2005-12 under Regulation (EC) N° 1829/2003); summary: http://www.efsa.eu.int/science/gmo/gm_ff_applications/more_info/809_en.html).

The Panel has requested additional information on the food/feed safety and the environmental risk assessment of GM maize 59122. The clock for this application has been stopped.

- GA21 maize (application EFSA-GMO-UK-2005-19 under Regulation (EC) N° 1829/2003); summary: http://www.efsa.eu.int/science/gmo/gm_ff_applications/more_info/1125_en.html).

The Panel has requested additional information on the food/feed safety of GM maize GA21. The clock for this application has been stopped.

The Panel had a discussion on the field trials included in the above applications. As stated in the EFSA GMO Panel Guidance Document (section 7.2) the applicant should provide data on comparative analyses between the GM plant and the most appropriate comparator that covers more than one representative growing season and multiple geographical locations representative of the various environments in which the GM plant will be cultivated.

12. UPDATE ON SELF TASK ACTIVITIES AND GUIDANCE ON GMO RISK ASSESSMENT

12.1. Self tasking activity on animal feeding trials

Two sub-working meetings were held on 17 March and 21 April 2006 to discuss the final chapters of the draft document, addressing the sensitivity and specificity of 90 day rodent feeding studies in the detection of unintended changes in a GM crop and the strategy for safety and nutritional testing of whole (GM) foods/feed.

12.2. Self tasking activity on the assessment of allergenicity of GM foods

A second meeting of the self task allergenicity of GM foods took place 3 April 2006, during which a first outline of issues (clinical aspects, bioinformatics, structural aspects, in vitro studies, analytical and profiling technology and animal models) to be considered in the draft document was discussed.

12.3. Risk Assessment of Plants Containing Genetic Modification Events Combined by Crossing

The document on the risk assessment of plants containing GM events combined by crossing (see the minutes of the 25th Plenary meeting for more details, http://www.efsa.eu.int/science/gmo/gmo_meetings/1424_en.html), will be published on the EFSA website for public consultation (http://www.efsa.europa.eu/science/gmo/gmo_consultations/1596_en.html).

13. FEEDBACK FROM GMO PANEL MEMBERS 2003-2006

The EFSA GMO panel will be renewed in June 2006. The outgoing Panel gave its feedback on working procedures and indicated, where appropriate, suggestions for improvement. The Panel has also been considering issues that could be addressed by the new Panel and which may help to evolve the risk assessment process. A comprehensive list is not provided but could include, for example:

- An evaluation of outputs from "omics" technologies as a potential tool for identifying any unintended effects thereby adding value to comparative analysis.
- An assessment of developing informatics tools to help predict possible interactions between genetic modifications e.g. interactions involving RNAi.
- A scoping exercise, carried out with appropriate collaborators, to assess the potential value of setting up a register containing essential information on the genetic modification in GMOs placed on the market (e.g. world wide, or CPB members of the party, or OECD member states). This could assist a risk assessment of possible interactions between a new GMO and those already on the market.

14. DATE OF FUTURE MEETINGS

Meeting dates were agreed at an earlier plenary meeting.

15. ANY OTHER BUSINESS

The Panel was informed about an FSA draft report of the working group on variation and uncertainty in toxicology that has been published on the FSA-website for public consultation: http://www.food.gov.uk/Consultations/ukwideconsults/2006/wgvutreport.