MINUTES OF THE 40TH PLENARY MEETING OF THE SCIENTIFIC PANEL ON GENETICALLY MODIFIED ORGANISMS HELD ON 12-13 MARCH 2008 IN PARMA, ITALY (ADOPTED ON 16 APRIL 2008)

AGENDA

PARTICIPANTS

GMO Panel:

Hans Christer Andersson, Salvatore Arpaia, Niels Bohse Hendriksen, Howard Davies, Lieve Herman, Sirpa Kärenlampi, Jozsef Kiss, Gijs Kleter, Ilona Kryspin-Sorensen, Harry Kuiper (Chair), Nickolas Panopoulos, Joe Perry, Willem Seinen, and Jean-Michel Wal.

EFSA:
GMO Unit: Elisa Bianco, Anna Christodoulidou, Yann Devos, Zoltan Diveki, Antonio Fernandez, Karine Lheureux, Sylvie Mestdagh, Claudia Paoletti, Suzy Renckens, Reinhilde Schoonjans and Ellen Van Haver.
IT Unit: Andre Malinowski[1].

European Commission:
Sabine Pelsser and Michael Walsh (DG SANCO), Chantal Bruetschy[2] and Bernadette Murray[1] (DG ENV).

APOLOGIES

GMO Panel:
Detlef Bartsch, Josep Casacuberta, Marc De Loose, Ingolf Nes, Annette Pöting, Joachim Schiemann and Jeremy Sweet.

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1. WELCOME AND APOLOGIES FOR ABSENCE

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

Gijs Kleter was welcomed as new Panel member. Dr. Kleter, who was already actively involved in the work of the GMO Panel as *ad hoc* expert to several EFSA working groups, introduced himself. His biography and his annual declaration of interest can be found on the EFSA website at: http://www.efsa.europa.eu/EFSA/ScientificPanels/GMO/efsa_locale-1178620753812_MembersAndWorkingGroup453.htm.

The Panel expressed its thanks and appreciation for the enthusiasm, commitment and professionalism shown by Dr. Suzy Renckens as Head of the EFSA GMO Unit. Dr. Renckens is leaving EFSA and this is a great loss for the GMO Panel. However, the Panel wished Dr. Renckens well in her future career, confident that her skills and experience will be used effectively by future employers.

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. No specific declarations of interest were declared.

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[1] Only present for agenda item 9.
[2] 12 March only.

4. ADOPTION OF THE MINUTES OF THE 39TH PLENARY MEETING HELD ON 30-31 JANUARY 2008

The minutes of the 39th plenary meeting (30-31 January 2008) were adopted as proposed and will be published at:

http://www.efsa.europa.eu/EFSA/efsa_locale-1178620753812_1178681574436.htm.

5. DISCUSSION AND POSSIBLE ADOPTION OF OPINIONS ON:

5.1. Carnation Moonaqua 123.8.12 (notification C/NL/06/01) under Directive 2001/18/EC

Introduction

EFSA 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 Moonaqua 123.8.12 for import 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 scientific objections raised by the Competent Authorities of the 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 Member States (MS) and from EFSA.

The scope of notification C/NL/06/01 is restricted to the import of cut flowers of carnation Moonaqua 123.8.12 for ornamental use only.

As a main conclusion, the opinion states that:

The carnation Moonaqua 123.8.12 has a modified flower colour, a shade of light mauve, which is achieved by introducing into cream-white carnation two genes of the anthocyanin biosynthesis pathway, one from Petunia and the other from Viola sp. Carnation Moonaqua 123.8.12 also expresses sulfonylurea herbicide tolerance.
The Panel has evaluated the molecular analysis of the genetically modified carnation Moonaqua 123.8.12 and concludes that the molecular characterisation of carnation Moonaqua 123.8.12 does not raise any safety concern for humans, animals or the environment.
Given the intended use of carnation Moonaqua 123.8.12 (excluding cultivation and human or animal consumption), the Panel considers that a compositional analysis limited to the newly synthesized anthocyanins is sufficient for the risk assessment of the intended modification. In the case of accidental consumption of petals from carnation Moonaqua 123.8.12, the amount of delphinidin and cyanidin consumed will be negligible in comparison with the amount present in fruits containing high levels of delphinidin and cyanidin, such as blackcurrant or red grapes. An aqueous extract from petals did not induce adverse effects in an acute oral toxicity study in mice and was not mutagenic in bacterial gene mutation tests. Furthermore, based on the results of bioinformatic studies, there is no evidence that any of the three proteins expressed is toxic or allergenic. The Panel concludes that carnation Moonaqua 123.8.12 is unlikely to have adverse effects on human or animal health in the unlikely event that carnation Moonaqua 123.8.12 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. In the event that this did occur, the consequences of the escape of the three genes would be negligible with regard to environmental impact. 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.europa.eu/en/science/gmo/gmo_opinions.html.

6. UPDATE ON APPLICATIONS RECEIVED UNDER DIRECTIVE 2001/18/EC, REGULATION (EC) NO 1829/2003 AND REGULATION (EC) NO 1831/2003

Ongoing applications

- NK603 maize (Application NL-2005-22 for cultivation): the Spanish Competent Authority who carries out the environmental risk assessment of NK603 maize in accordance with Article 6.3(c) and 19.3(c) of Regulation (EC) No 1829/2003, has received additional information from the applicant following its request (see item 6.2 of the minutes of the 31st plenary meeting[3]). The Spanish Competent Authority will present its environmental risk assessment report at the next plenary meeting of the GMO Panel.

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

7.1. Safeguard measure invoked by France in relation to MON 810 maize

France has adopted an Order which suspends the cultivation of seed varieties of MON 810 pending a decision on the application of the reauthorisation of the product. This Order was notified to the Commission as a safeguard measure under Article 23 of Directive 2001/18/EC. In the meantime, France also notified to the Commission a note titled "Emergency measure" under Article 34 of Regulation (EC) No 1829/2003.

EFSA received from the Commission a request, under Article 29(1) and in accordance with Articles 22(2) and 22(5)(c) of Regulation (EC) No 178/2002, to assess:

- The opinion of the 'Comité de préfiguration" of the High Authority for GMOs, dated 9 January 2008.
- The French position that the justifications presented by Monsanto on 30 January 2008 are not sufficient to invalidate the data of the French Order.
- The scientific evidence which is presented in the accompanying note of the Order.
- The scientific justification of the duration of the measure, which is linked to the ongoing procedure of the notification for the renewal of MON810.

[3] http://www.efsa.europa.eu/EFSA/efsa_locale-1178620753812_1178620775268.htm.

EFSA has sent an answer to the Commission following its request, indicating that the Panel will provide a scientific opinion on the measure taken by France by the end of April 2008, subject to the receipt of a comprehensive data package (literature references listed in the above mentioned opinion of the 'Comité de préfiguration", as well as the argumentation of the French position towards the justifications presented by Monsanto).

As regards the renewal of the market authorisation of maize MON 810 for cultivation (EFSA-GMO-RX-MON810) under Regulation (EC) No 1829/2003, the Panel will issue an opinion in accordance with the provisions of Regulation (EC) No 1829/2003. The evaluation of this renewal application will be performed in close collaboration with the Spanish Competent Authority, who will carry out the initial evaluation of the environmental risk assessment in accordance with Articles 6.3(c) and 18.3(c) of Regulation (EC) No 1829/2003.

7.2. Danisco Xylanase G/L (endo-1,4-beta-xylanase) – Request for an updated opinion (EFSA-Q-2008-021)

EFSA received a request from the Commission for an updated scientific opinion on the safety of the enzyme preparation of trade name "Danisco Xylanase G/L (endo-1-4-beta-xylanase)" as a feed additive for laying hens and chickens and ducks for fattening.

An opinion on "Danisco Xylanase" was adopted in September 2007[4] as a co-opinion of the FEEDAP and GMO Panels. In the opinion it was concluded that "fragments of recombinant DNA are present in the final concentrate only in trace amounts". This was considered by the Commission as not complying with Article 7(3)(i) of Regulation (EC) No 1831/2003. Therefore, the Commission has asked for further information from the company on this issue.

In view of the above, the Commission asks EFSA to deliver an opinion on the safety of this enzyme preparation as feed additive taking into account its earlier opinion of September 2007 and the new data submitted.

8. UPDATE ON SELF TASKING ACTIVITIES AND GUIDANCE ON GMO RISK ASSESSMENT

8.1. EC guidelines and update EFSA guidance document

Following the request from DG SANCO to establish EC guidelines for the risk assessment of GM plants (for which the EFSA guidance document[5] is used as a starting point; see also item 7.4 of the minutes of the 39th plenary meeting, item 7.2 of the minutes of the 38th plenary meeting and item 10 of the minutes of the 37th plenary meeting), the working group of the Panel on molecular characterisation met on 21-22 February and the working group on food/feed safety on 13 February 2008 to discuss issues in the EFSA guidance document that could be further elaborated and clarified, taking into account scientific progress and outcomes of self tasking activities. The ongoing self tasking activity on statistics will have its next meeting end of April during which issues of field trial design will be further discussed with the aim of updating the EFSA guidance document with regard to the statistical analysis.

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[4] http://www.efsa.europa.eu/EFSA/efsa_locale-1178620753812_1178654544327.htm.

[5] Guidance document of the GMO Panel for the risk assessment of genetically modified plants and derived food and feed (http://www.efsa.europa.eu/EFSA/efsa_locale-1178620753812_1178620775747.htm).

EFSA has sent a letter to the Commission (DG SANCO) indicating that the deadline for revising the guidance document by early March cannot be met given further discussions they require in the respective working groups, and the ongoing work on GMO applications that need to be assessed within the legal timeframe. The adoption of the revised guidance document at the Plenary meeting of 21-22 May 2008 has therefore been proposed as a new deadline.

With regard to the request from the Commission (DG ENV) for establishing guidelines in the area of environmental risk assessment (see item 9 of the minutes of the 39th plenary meeting), the working group on environmental risk assessment of the GMO Panel has discussed at its latest working group meeting a mandate with representatives of DG ENV. The EFSA guidance document with regard to the environmental risk assessment will be updated within a timeframe of 24 months, along the work of the self tasking activity for assessing the impacts of GM plants on non-target organisms.

8.2. Statistical considerations in the safety evaluation of GMOs

The next working group meeting is scheduled for 28th April 2008.

8.3. Allergenicity assessment of GM foods

The next working group meeting will take place on 7th April 2008, linked to a visit to the Joint Research Centre (JRC) of the European Commission on the 8th April 2008 to be informed about the GMO DNA sequence database integrated with bioinformatics tools for similarity searches (see item 9 of the minutes of the 39th plenary meeting) within the frame of the allergenicity assessment of GMO applications.

8.4. Guidance for the assessment of GM plants used for non-food/feed purposes

Comments were received from the European Commission and the European Medicines Agency (EMEA) on the draft opinion on 'the risk assessment of GM plants used for non-food or non-feed purposes' as adopted by the Panel at its 37th Plenary meeting of 22-23 November 2007 (see item 5.1 of the minutes of the 37th Plenary meeting). These comments will be considered before the report will be published on the EFSA website for public consultation.

8.5. Animal feeding trials

The report on the "Safety and nutritional assessment of GM plants and derived food and feed: The role of animal feeding trials" of the self tasking working group on animal feeding trials, and which was adopted by the Panel on 12 September 2007, has been published in Food and Chemical Toxicology 46 (2008) S1 – S70, and is accessible from the EFSA website at: http://www.efsa.europa.eu/EFSA/efsa_locale-1178620753812_1178660555237.htm.

9. FEEDBACK FROM EFSA AND THE SCIENTIFIC COMMITTEE

The Panel was informed about the possibilities of Audio/Web and Telephone conferencing (Live Meeting), hosted by EFSA, which allows experts to participate in virtual meetings from their office, and at the same time allowing them to share and work on the same documents.

10. FEEDBACK FROM THE COMMISSION

A meeting of the OECD Task Force for the Safety of Novel Foods and Feeds is scheduled for 8-10 April 2008, for which the Commission has asked EFSA for assistance. Gijs Kleter will present the EFSA GMO activities as GMO Panel member on behalf of EFSA.

The Commission representative provided the Panel with the status of applications that have been presented to the Standing Committee on the Food Chain and Animal Health for possible authorisation, and for which no qualified majority was reached.

11. DATES OF FUTURE MEETINGS

Meeting dates were agreed at earlier plenary meetings.

12. ANY OTHER BUSINESS

No other business was discussed.