MINUTES OF THE 31ST PLENARY MEETING OF THE SCIENTIFIC PANEL ON GENETICALLY MODIFIED ORGANISMS HELD ON 31 JANUARY – 1 FEBRUARY 2007 (ADOPTED ON 22 MARCH 2007)

AGENDA

PARTICIPANTS

GMO Panel:
Hans Christer Andersson, Salvatore Arpaia, Detlef Bartsch, Josep Casacuberta, Howard Davies, Ralf Einspanier, Niels Bohse Hendriksen, Lieve Herman, Sirpa Kärenlampi (Vice-Chair), Jozsef Kiss, Ilona Kryspin-Sorensen, Harry Kuiper (Chair), Nickolas Panopoulos, Joe Perry, Annette Pöting, Joachim Schiemann, Willem Seinen, Jeremy Sweet (Vice-Chair) and Jean-Michel Wal.

EFSA:
GMO Unit: David Carlander, Ana Gomes, Karine Lheureux, Sylvie Mestdagh, Claudia Paoletti, Suzy Renckens, Reinhilde Schoonjans, Ellen Van Haver.

European Commission:
Sébastien Goux (DG SANCO) and Michael Walsh (DG SANCO).

APOLOGIES

GMO Panel:
Marc De Loose and Ingolf Nes.

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1. WELCOME AND APOLOGIES FOR ABSENCE

The Chair opened the meeting and welcomed all. Apologies for absence were received from Marc De Loose and Ingolf Nes.

2. ADOPTION OF THE AGENDA

The agenda was adopted as proposed.

One of the Panel members, Prof. Ralf Einspanier, resigned from the Panel because the workload of his daily activities was no longer compatible with that of the GMO Panel. A new GMO Panel member will be selected from the reserve list.

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.

4. ADOPTION OF THE MINUTES OF THE 30TH PLENARY MEETING HELD ON 5-6 DECEMBER 2006

The minutes of the 30th plenary meeting (5-6 December 2006) were adopted as proposed and will be published at:

http://www.efsa.europa.eu/en/science/gmo/gmo_meetings/gmo_30th_plenmeet.html.

5. DISCUSSION AND POSSIBLE ADOPTION OF OPINIONS ON:

5.1. QuantumTM Phytase 5000 L and QuantumTM Phytase 2500 D (6-phytase)

Introduction

Within the framework of Regulation (EC) N° 1831/2003, EFSA has been requested to deliver an opinion on the efficacy and the safety for the target animals, the consumer, user and the environment of the product Quantum^{TM} Phytase which is a preparation of 6- phytase (EC 3.1.3.26), produced by the genetically modified micro-organism *Pichia pastoris* (DSM 15927), 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 the molecular characterization of the genetic modification does not trigger any particular safety concerns. Both the donor and recipient organisms are considered safe. The final enzyme preparation contains no cultivable producer organisms, no antimicrobial activity or mycotoxins, and the level of the newly introduced DNA is below the limit of detection.

Adoption

The opinion with regard to the risk assessment of the genetic modification of the application was adopted unanimously by the Panel. Once the other part has been adopted by the FEEDAP Panel, the co-opinion will be published 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

6.1. Past scientific opinions

EFSA received a request from Belgium for complementary information on applications EFSA-GMO-UK-2005-05, EFSA-GMO-UK-2004-06 and EFSA-GMO-BE-2004-07 submitted under Regulation (EC) 1829/2003. The questions are complementary to the Belgian comments submitted during the commenting period foreseen for nominated risk assessment bodies and national competent authorities.

The response of the Panel will be sent to the Belgian Competent Authority.

6.2. Ongoing applications

- The Panel discussed shortly the structure of the opinions, which currently address the comments from the Member States in the main text as well as in the annex to the opinion (Member States' comments are addressed individually in the annex according to EFSA's visibility/transparency policy[1] following a request from the European Commission). The Panel concluded to continue the use of the current structure.

- MIR604 maize (Application UK-2005-11): following the request from the GMO Panel for additional information (see minutes of 25th Plenary meeting[2]), the applicant provided further data (received on 30 January 2007) which will be assessed by the Working Group in charge of Food/Feed assessment.

- NK603 maize (Application NL-2005-22 for cultivation[3]): The Panel discussed the questions to be sent to the applicant for additional information on the environmental risk assessment of NK603 maize as identified by the Spanish Competent Authority which carries out the environmental risk assessment of NK603 maize in accordance with Article 6.3(c) and 19.3(c) of Regulation (EC) 1829/2003.

- 59122 maize (Application NL-2005-23 for cultivation[3]): Questions to the applicant for additional information on the environmental risk assessment were identified by the Panel and the Dutch Competent Authority. The assessment of this application is linked to that of application NL-2005-12 (same transformation event) for which additional data have been requested.

- NK603 x MON810 maize (Application NL-2005-26 for cultivation[3]): The Panel discussed the questions to be sent to the applicant for additional information on the environmental risk assessment of NK603 x MON810 maize as identified by the French Competent Authority.

7. JOINT MEETING BETWEEN THE NATIONAL COMPETENT AUTHORITIES AND GMO PANEL MEMBERS

Experts from France, Germany, Spain and the Netherlands met with members of the Panel on 30th January 2007. These four countries have volunteered to carry out the initial environmental risk assessments of one of the following applications for cultivation in accordance with Article 6.3(c) and 19.3(c) of Regulation (EC) 1829/2003: UK-2005-17, NL-2005-22, NL-2005-23, NL-2005-24 and NL-2005-26.

The aim of this meeting was to share experiences on the environmental risk assessments of these five applications and to discuss the evaluation of data presented in the applications and the risk assessment of herbicide tolerant and insect resistant GM crops. In addition, a common approach with these Member States was discussed in carrying out environmental risk assessments in line with EFSA's guidance document[4]. Regular bilateral meetings with the Member States involved in the initial risk assessment of specific applications will continue to be held in the future.

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[1] See point 7.1 of the minutes of the 28th Plenary meeting (http://www.efsa.europa.eu/en/science/gmo/gmo_meetings/gmo_28th_plenmeet.html)

[2] http://www.efsa.europa.eu/en/science/gmo/gmo_meetings/1424.html

[3] In accordance with Article 6.3(c) and 19.3(c) of Regulation (EC) 1829/2003, the initial environmental risk assessment is carried out by a Member State.

[4] http:/www.efsa.europa.eu/en/science/gmo/gmo_guidance/660.html

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

8.1. Applications under Regulation (EC) No 1831/2003

EFSA received from the European Commission a request for a scientific opinion on GMO-derived enzymatic preparation Avizyme 1505 as a feed additive for chickens for fattening and ducks for fattening in accordance with Regulation (EC) No 1831/2003. For applications within the remit of two Panels (GMO and FEEDAP), the GMO Panel will perform the risk assessment of the genetic modification event and will draft a co-opinion with the FEEDAP Panel.

9. WORKING PROCEDURES OF THE GMO PANEL

The Panel is in favor of holding telephone- and web-conference meetings when required for the discussion of applications and specific topics of self tasking activities which involve a small number of working group members. The involvement of EFSA and the Panel in international activities organized by OECD, FAO/WHO, Codex Alimentarius… was considered important as EFSA should play a proactive role in this kind of activities. The Panel also discussed the possibility of publishing activities of the Panel in peer reviewed papers. A common approach needs to be set up. In this regard, the Panel stressed the importance of improving the visibility of the EFSA Journal in the scientific world.

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

10.1. Allergenicity assessment of GM foods

A sub-working group meeting was held on 26 January 2007 to discuss the use of animal models for predicting the possible allergenicity of GM foods/feed. Experts with expertise in this field have been invited for this specific meeting. Other sub-working group meetings are foreseen to discuss specific topics, such as bioinformatics and clinical aspects for the allergenicity assessment of GM foods/feed.

10.2. Statistical considerations in the safety evaluation of GMOs

A working group meeting of the self tasking activity on statistics was held on 11 December 2006. EFSA has approached applicants for the possibility of using datasets that can be found in GM plant applications. The aim of using these data is to assess statistical approaches and increase harmonization of approaches regarding the performance of field trials, analysis of compositional data and data of animal experiments.

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

A sub-working group meeting was held on 23-24 January 2007 to discuss further the issues of toxicity and allergenicity, and compositional analysis of GM plants used for non-food/feed purposes. The next meeting with the whole working group is scheduled for 1-2 March 2007.

10.4. Animal feeding trials

The ongoing public consultation on the draft report "Safety and nutritional assessment of GM plant derived foods/feed – The role of animal feeding trials" was extended by two weeks, bringing the period for public consultation to 8 weeks. The extended deadline was set for 15 February 2007 (http://www.efsa.europa.eu/en/science/gmo/gmo_consultations/gmo_AnimalFeedingTrials.html).

10.5. Risk assessment of plants containing genetic modification events combined by crossing

A working group consisting of members of the working groups of the GMO Panel on molecular characterisation, food/feed safety and environmental risk assessment will finalise the document on "risk assessment of plants containing genetic modification events combined by crossing" following the comments received from the public consultation (see item 12.3 of the minutes of the 26th Plenary meeting[5]).

11. FEEDBACK FROM EFSA AND THE SCIENTIFIC COMMITTEE

The Panel was informed about the EFSA public consultation on the Qualified Presumption of Safety (QPS) approach for the safety assessment of microorganisms deliberately added to food and feed
(http://www.efsa.europa.eu/en/science/sc_commitee/sc_consultations/sc_consultation_qps.html).
The deadline for commenting is 5 March 2007.

The Chairman gave an overview of the outcome of the 22nd Plenary meeting of the Scientific Committee held on 14-15 December 2007. The minutes of this meeting will be published at: http://www.efsa.europa.eu/en/science/sc_commitee/sc_meetings/22nd_sc_meeting.html.

A list of competent organisations designated by the Member States and which may assist EFSA within the framework of Article 36 of EFSA's founding Regulation (EC) 179/2002 has been published on the following website: http://www.efsa.europa.eu/en/about_efsa/cooperation.html. The Panel identified possible issues to be proposed under Article 36, such as a study on the toxicity and the environmental impact of novel Cry proteins, on the state of the art on the impact of herbicide tolerant GM plants on non-target organisms and on the selection of indicator species and/or surrogate species representing key ecological functional groups for testing non-target effects of GMOs vs. pesticide use. The forthcoming EFSA colloquium on environmental risk assessment will be useful in identifying priority needs.

12. FEEDBACK FROM THE EUROPEAN COMMISSION

The Panel was informed about the outcome of the sixth session of the Codex *Ad Hoc* Intergovernmental Task Force on Foods derived from Biotechnology, which was held in Chiba, Japan from 27 November to 1 December 2006. Christer Andersson, who presented the Swedish Competent Authority, has been assisting the Commission as GMO Panel member on behalf of EFSA. The Commission indicated that a Codex working group meeting on "low-level presence of recombinant DNA plant material in food resulting from asynchronous authorisations" will take place on 13-15 March 2007 and on "foods derived from recombinant-DNA plants modified for nutritional or health benefits" on 7-9 May 2007. The Commission is asking for EFSA's support and participation in these activities.

[5] http://www.efsa.europa.eu/en/science/gmo/gmo_meetings/1483.html

13. DATES OF FUTURE MEETINGS

Meeting dates were agreed at earlier plenary meetings.

14. ANY OTHER BUSINESS

- The draft approach as proposed by the Panel to be followed in the frame of the environmental risk assessment of GM herbicide-tolerant crops associated with the applications of the corresponding herbicides[6] was discussed with the participants of the joint meeting of Competent Authorities on 30 January 2007 (see item 7). The proposed approach suggests that applicants and the competent authorities in the Member States establish and implement herbicide management systems for GM herbicide-tolerant crops that pose no more harm than conventional systems and are consistent with environmental protection goals and biodiversity action plans in each Member State. The PPR Panel and PRAPER Unit of EFSA will be asked for their view. In a next step, the Commission will be consulted on the issue of risk management and legislative aspects of the interplay between Directives 2001/18/EC and 91/414/EEC.

- EFSA received a letter from the Dutch competent authority (COGEM, Commissie Genetische Modificatie) concerning their advice issued on Post Market Environmental Monitoring (PMEM) of GM crops in the Netherlands. COGEM would like to make the Panel aware of one difference between their advice and the opinion of the GMO Panel on PMEM[7] concerning the processing of data originating from the monitoring activities. This issue relates to a management issue. The Panel will prepare a reply to the COGEM letter.

- EFSA and the GMO Panel will organise a scientific hearing with applicants on 21 March 2007 to learn about new forthcoming developments in the area of plant biotechnology which may lead to further issues to be addressed in the risk assessment (e.g. guidance documents, self tasking activities). Procedural and legislative matters will be outside the scope of this meeting.

- The Panel discussed briefly the draft agenda of the EFSA Colloquium on environmental risk assessment which is scheduled for 20-21 June 2007 in Parma.

- Within the framework of the authorization procedure for the placing on the market of GM potato EH92-527-1 under Regulation (EC) 1829/2003, the Commission sent a request to EMEA for their view on the current or possible uses of antibiotics for which the nptII gene confers resistance and whether current uses are in line with the earlier opinion of the GMO Panel on antibiotic resistance marker genes[8] (ARMGs). In this opinion, the Panel has evaluated the potential risks associated with specific ARMGs taking into account the likely occurrence of horizontal gene transfer from GM plants to microbes, the potential impact of horizontal gene transfer where naturally occurring resistance to the relevant antibiotics exists in the microbial gene pool and their current use in clinical and veterinary medicine. These factors will impact on

[6] See the minutes of the 30th Plenary meeting (http://www.efsa.europa.eu/en/science/gmo/gmo_meetings/gmo_30th_plenmeet.html)
[7] http://www.efsa.europa.eu/en/science/gmo/gmo_opinions/1381.html
[8] http://www.efsa.europa.eu/en/science/gmo/gmo_opinions/384.html

the likelihood of any adverse effects on humans or the environment of ARMGs used in GM plants.
The GMO Panel regrets that the Commission has not opted for a joint consultation of EMEA and EFSA to facilitate the scientific discussion on the safety of the use of the nptII marker gene.

- EFSA received via the European Commission a letter from Austria (Bundesministerium für Gesundheit und Frauen) containing a report on the risk assessment of "stacked events". This report will be considered in the further development of guidance documents by the GMO Panel.
