MINUTES OF THE 39TH PLENARY MEETING OF THE SCIENTIFIC PANEL ON GENETICALLY MODIFIED ORGANISMS HELD ON 30-31 JANUARY 2008 IN PARMA, ITALY (ADOPTED ON 12 MARCH 2008)

AGENDA

PARTICIPANTS

GMO Panel:

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

EFSA:

GMO Unit: Anna Christodoulidou, Zoltan Diveki, Ana Gomes, Karine Lheureux, Sylvie Mestdagh, Claudia Paoletti, Suzy Renckens, Reinhilde Schoonjans and Ellen Van Haver.

European Commission:
Sébastien Goux, Sabine Pelsser and Michael Walsh (DG SANCO), Chantal Bruetschy[1] (DG ENV), Guy Van den Eede[2] (JRC).

APOLOGIES

GMO Panel:
Niels Bohse Hendriksen, 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 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. No specific declarations of interest were declared.

4. ADOPTION OF THE MINUTES OF THE 38TH PLENARY MEETING HELD ON 18-19 DECEMBER 2007

The minutes of the 38th plenary meeting (18-19 December 2007) were adopted as proposed and will be published at:

http://www.efsa.europa.eu/EFSA/efsa_locale-1178620753812_1178636421629.htm.

5. DISCUSSION AND POSSIBLE ADOPTION OF OPINIONS ON:

5.1. L-Valine (FAD-2007-0015 under Regulation (EC) 1831/2003; GMO/FEEDAP co-opinion)

Introduction

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[1] 30 January only.
[2] Only present for agenda item 9.

Within the framework of Regulation (EC) N° 1831/2003, EFSA has been requested to deliver an opinion on the efficacy and the safety for all animal species, user and consumer and the environment of the product L-Valine, which is a preparation of L-Valine produced by fermentation of a genetically modified strain of *E. coli* 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 additive. The FEEDAP Panel will assess all other parts of the application.

It was considered that the introduced genes do not trigger any particular safety concerns. The final preparation contains no cultivable producer organisms 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.

5.2. T45 oilseed rape (applications EFSA-GMO-UK-2005-25 and EFSA-GMO-RX-T45) under Regulation (EC) 1829/2003

Introduction

The Panel was requested in accordance with Articles 6(6) and 18(6) of Regulation (EC) No 1829/2003, to carry out a scientific assessment of T45 oilseed rape and all derived products for food and feed uses, import and processing (EFSA-GMO-UK-2005-25).

Within the framework of the same Regulation, EFSA received from the European Commission an application for renewal of the authorisation of T45 oilseed rape (EFSA-GMO-RX-T45). This application covers the continued marketing of existing food additives, feed materials produced from T45 oilseed rape.

All data required for the risk assessment of the application EFSA-GMO-RX-T45 have also been provided in application EFSA-GMO-UK-2005-25.

The Panel performed one single comprehensive risk assessment for all intended uses of genetically modified T45 oilseed rape and issued a single comprehensive scientific opinion for both applications.

The opinion of the Panel corresponds to the safety assessment report as referred to in Articles 6(6) and 18(6) of Regulation (EC) No 1829/2003 and will be part of the overall EFSA opinion as required by Articles 6(5) and 18(5) of Regulation (EC) No 1829/2003.

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 comments from MS that were submitted during the three-month consultation period were addressed individually by the Panel in a separate annex.

The Panel is of the opinion that the molecular characterisation provided for the transformation event T45 is sufficient for the safety assessment. The bioinformatic analysis of the inserted DNA and flanking regions does not raise any safety concern. The expression of the genes introduced by genetic modification has been sufficiently analysed and the stability of the genetic modification has been demonstrated over several generations. The panel considers that the molecular characterization does not indicate any safety concern.

The comparative analyses showed no biologically relevant agronomic and compositional changes in T45 oilseed rape. The Panel is of the opinion that T45 oilseed rape is as safe as its non GM counterparts and that the overall allergenicity of the whole plant is not changed through the genetic modification.

A 42-day feeding study using broilers did not indicate differences in the nutritional value of T45 oilseed rape versus the non-GM comparator.

The application EFSA-GMO-UK-2005-25 is for food and feed uses, import and processing of oilseed rape T45 and all derived products. The application EFSA-GMO-RX-T45 covers the continued marketing of existing food additives and feed materials produced from oilseed rape T45. There is therefore no requirement for scientific information on possible environmental effects associated with the cultivation of the GM oilseed rape T45 in the EU. The GMO Panel is of the opinion that the likelihood of the spread and establishment of oilseed rape T45 is very low and that unintended environmental effects due to this GM oilseed rape will not be different from those of conventional oilseed rape varieties. The scope of the monitoring plan provided by the applicant is in line with the intended uses of oilseed rape T45. The Panel advises that appropriate management systems should be in place to minimise accidental loss and spillage of transgenic oilseed rape during transportation, storage, handling in the environment and processing into derived products.

In conclusion, the Panel considers that information available for oilseed rape T45 addresses the comments raised by the Member States and considers it unlikely that oilseed rape T45 will have any adverse effect on human and animal health or on the environment in the context of its proposed uses.

Adoption

The opinion was adopted unanimously by the Panel. The opinion and the table containing the responses of the Panel to MS comments (Annex G of the overall opinion) can be found on the following EFSA website at:
http://www.efsa.europa.eu/EFSA/ScientificPanels/GMO/efsa_locale-1178620753812_GMOOpinions455.htm

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

Ongoing applications

- Carnation Moonaqua 123.8.12 (notification C/NL/06/01): EFSA received the answer from the applicant to the request from the Panel for clarification of the variation in morphological characteristics of Carnation Moonaqua. The additional information will be further assessed at the next Food/Feed working group.

Interpretation of EFSA's guidance document

- The Panel wishes to clarify the requirements for the comparative assessment of herbicide tolerant plants as described in Section 7.2 of the EFSA Guidance Document[3]. It is stated that: "the basic set of data should be obtained from a comparison of the GM plant and the most appropriate control line grown in the same field under comparable conditions". The principle remains that GM plants and the near isogenic comparator should be exposed to the same herbicide treatment(s). Clearly, in the case of GM plants tolerant to glyphosate or glufosinate, the near-isogenic comparator cannot be treated with these broad-spectrum herbicides. In that case, it is recommended to include GM plants exposed to the intended herbicide and in addition to this, GM plants exposed to the same conventional herbicide(s) as the control plants.

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

7.1. New self-tasking activity for assessing the impacts of GM plants on non-target organisms

The draft mandate for establishing a self-tasking activity for assessing the impacts of GM plants on non-target organisms, as was adopted by the Panel at its last plenary meeting of 18-19 December 2007 (see agenda item 7.1 of the minutes of the 38th Plenary meeting[4]), was slightly amended to include some aspects related to further risk assessment guidance in connection to the EC Action Plan on GMOs (see item 9 further below).

7.2. Statistical considerations in the safety evaluation of GMOs

A working group meeting took place 24 January 2008 during which the draft report was further discussed and to which some structural changes were proposed (the sections on the analysis of field trial and animal data will for instance be separated). The working group has been requested by the GMO Panel to provide support for the elaboration of the EC guidelines with regard to the definition of field trial design for collecting data suitable for the statistical analysis.

7.3. Allergenicity assessment of GM foods

A working group meeting was held on 23 January 2008 in London. The aim of that meeting was to focus on conclusions and recommendations for each chapter. In addition, a case study was discussed for assessing the *de novo* sensitising potential of a protein that belongs to a protein family which comprises numerous common allergens, while there is no or low sequence homology, and consequently unlikelihood for cross reactivity, with known allergens.

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[3] 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).

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

7.4. EC guidelines and update EFSA guidance document

Following the request from DG SANCO to establish EC guidelines for the risk assessment of GM plants (see item 7.2 of the minutes of the 38th plenary meeting and item 10 of the 37th plenary meeting), some Panel members representing the two standing working groups of the GMO Panel (molecular characterisation and food/feed safety) met on 15-16 January 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 on the role of animal feeding trials in the safety and nutritional assessment of GM plants and on the risk assessment of stacked events. Updates in the field of statistical analysis will be taken into account where possible as the self tasking activity on statistics is still ongoing. Further meetings of the molecular characterisation and food/feed safety will be organised in February. The Panel however noted that the request from the Commission for establishing EC guidelines (for which the EFSA guidance document is used as a starting point) cannot be combined with the work on GMO applications given the already high workload of the Panel. A timeline needs therefore to be agreed upon with the Commission.

8. FEEDBACK FROM EFSA AND THE SCIENTIFIC COMMITTEE

The Panel was informed about a proposal from the Scientific Committee for a review system for EFSA's scientific activities, which is comprised of a self-review, an internal and an external scientific review. The Panel will consider at one of its next meetings how to proceed with the review of GMO opinions.

9. FEEDBACK FROM THE COMMISSION

Guy Van den Eede, Head of the Biotechnology and GMOs Unit of the Joint Research Centre (JRC), gave a presentation of the Central Core Sequence Information System (CCSIS), implementing a GMO DNA sequence database that is integrated with Bioinformatics Tools for similarity searches. Sequence data enclosed in GMO-dossiers that are received by the Community Reference Laboratory for GM food and Feed (CRL) and by EFSA are stored in the database and homology searches can be done against public databases and the JRC GMO sequence databank in a confidential environment. A meeting will be organized at JRC with representatives of the working groups of the GMO Panel on molecular characterization and allergenicity assessment to test the value of the databank for the risk assessment of GMO applications.

EFSA has received a letter from the European Commission (DG ENV) with a mandate for establishing four different guidelines in the area of the environmental risk assessment. Chantal Bruetschy, Head of the Biotechnology & Pesticides Unit of DG ENV, explained that this letter is in accordance with Action 4 of the EC Action plan and is in analogy with the request from DG SANCO for implementing guidelines for the risk assessment (see also item 10 of the minutes of the 37th plenary meeting). The Panel expressed some reservations with respect to the proposed mandate which was also discussed at the last meeting of the working group on environmental risk assessment of the GMO Panel. It was agreed with Mrs. Bruetschy that the working group on environmental risk assessment will further discuss this topic together with DG ENV at its next working group meeting to agree on a common mandate.

10. DATES OF FUTURE MEETINGS

The following plenary meetings have been scheduled for 2008: 12-13 March, 16-17 April, 21-22 May, 2-3 July, 10-11 September (back to back to the meeting of the European Advisory Committees on Biosafety (MEACB) in Berlin), 29-30 October, and 3-4 December.

11. ANY OTHER BUSINESS

The Panel was informed about the final report of the Special Advisory Forum meeting on GMO Risk Assessment that was held on 13 November 2007, which has been published on the following EFSA website:
http://www.efsa.europa.eu/EFSA/efsa_locale-1178620753812_1178656904823.htm.

The Panel was informed about a letter from EFSA to the Director Generals of DG SANCO (Robert Madelin) and DG ENV (Carl Mogens) referring to the EC draft decisions on the cultivation of GM maize 1507 and Bt11 (see also item 10 of the minutes of the 38th Plenary meeting), and the recent developments related to the safeguard measure by France on MON810 maize. With regard to the latter, the EFSA Executive Director has asked the Panel to consider thoroughly the scientific studies and publications that are referred to in the opinion of the "Comité de préfiguration de la Haute Autorité". The GMO Panel working group on environment has considered the scientific studies and publications at its last meeting and is not aware of any scientific data which require a re-assessment of Bt maize applications or amendment of previous scientific opinions on the safety of Bt maize, including the opinions on safeguard clauses[5]. The Panel will carry out the full environmental risk assessment of MON 810 maize (application EFSA-GMO-RX-810) within the frame of renewal of authorisations of existing products according to Articles 11 and 23 of Regulation (EC) No 1829/2003.

EFSA has received comments from an applicant regarding the EFSA guidance document for the risk assessment of GM plants containing stacked transformation events[6]. These comments will be further considered during the update of the EFSA guidance document on GM plants (see item 7.4).

The draft document on the environmental risk assessment of GM herbicide tolerant plants and the interplay between Directive 2001/18/EC and Directive 91/414/EC, that was discussed by the Panel at its 36th Plenary meeting[7] (see item 12) is being considered by the EFSA hierarchy for approval, following which the European Commission will be consulted.

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[5] Austrian invoke of Article 23 of Directive 2001/18/EC (http://www.efsa.europa.eu/EFSA/efsa_locale-1178620753812_1178620771094.htm), GM crops (Bt176 maize, MON810 maize, T25 maize, Topas 19/2 oilseed rape and Ms1xRf1 oilseed rape) subject to safeguard clauses (http://www.efsa.europa.eu/EFSA/efsa_locale-1178620753812_1178620769622.htm), safeguard clause invoked by Greece (http://www.efsa.europa.eu/EFSA/efsa_locale-1178620753812_1178620768611.htm).

[6] http://www.efsa.europa.eu/EFSA/efsa_locale-1178620753812_1178623591786.htm.

[7] http://www.efsa.europa.eu/EFSA/efsa_locale-1178620753812_1178656961668.htm.