MINUTES OF THE 36TH PLENARY MEETING OF THE SCIENTIFIC PANEL ON GENETICALLY MODIFIED ORGANISMS HELD ON 30-31 OCTOBER 2007 IN PARMA, ITALY (ADOPTED ON 22 NOVEMBER 2007)

AGENDA

PARTICIPANTS

GMO Panel:

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

Ad Hoc experts:
Gijs Kleter[1] (Wageningen University and Research Centre, RIKILT).

EFSA:
GMO Unit: Anna Christodoulidou, Zoltan Diveki, Claudia Paoletti, Reinhilde Schoonjans and Ellen Van Haver.

European Commission:
Sabine Pelsser (DG SANCO).

APOLOGIES

GMO Panel:
Niels Bohse Hendriksen, Marc De Loose, Harry Kuiper, Joachim Schiemann and Jean-Michel Wal.

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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 35TH PLENARY MEETING HELD ON 12-13 SEPTEMBER 2007

The minutes of the 35th plenary meeting (12-13 September 2007) were adopted as proposed and will be published at:

http://www.efsa.europa.eu/EFSA/efsa_locale-1178620753812_1178636420918.htm.

5. DISCUSSION AND POSSIBLE ADOPTION OF OPINIONS ON:

5.1. LLRice62 (application EFSA-GMO-UK-2004-04 under Regulation (EC) No 1829/2003)

Introduction

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[1] For agenda item 8 only.

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 the genetically modified rice LLRice62 for food and feed uses, import and processing.

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 draft opinion and the table with comments from MS were presented to the Panel members during the plenary meeting followed by a discussion on outstanding issues.

The Panel is of the opinion that the molecular characterisation of the DNA insert and flanking regions in LLRICE62 does not raise safety concerns, and sufficient evidence for the stability of the insert structure and of the newly introduced trait was provided. Comparative analysis has shown that LLRICE62 is compositionally and agronomically equivalent to conventional rice, except for the introduced transgenic trait. The risk assessment included an analysis of data from analytical studies, bioinformatics, and *in vitro* and *in vivo* studies. The Panel concluded that the LLRICE62 is as safe as its non-GM comparator and that the overall allergenicity of the whole plant is not changed.

The application EFSA-GMO-UK-2004-04 is for food and feed uses, import and processing. There is therefore no requirement for scientific information on possible environmental effects associated with the cultivation of LLRICE62. Considering the scope of the application, not for cultivation, the Panel is of the opinion that unintended environmental effects due to this rice will be no different from that of conventional rice varieties. There is a likelihood of spillage and subsequent spread and establishment of LLRICE62 during transport of paddy rice and the Panel advises that appropriate management systems should be in place to prevent seeds of LLRICE62 entering cultivation. The scope of the monitoring plan provided by the applicant and the reporting intervals are in line with the intended uses of LLRICE62 since cultivation is excluded.

In conclusion, taking into account issues raised by Member States, the Panel considers that, on the basis of the information available for LLRICE62, it is unlikely that LLRICE62 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/efsa_locale-1178620753812_1178620784584.htm.

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

Ongoing applications

- MIR604 Maize (application UK-2005-11): the Panel identified the issues on which insufficient data were provided by the applicant. A final letter will be sent to the applicant indicating the missing information and clarifying that without receiving the full information the Panel will not be able to complete the food/feed safety assessment of MIR604 maize.

- Soybean 40-3-2 for cultivation (application NL-2005-24): following the questions from the German Competent Authority, who is carrying out the environmental risk assessment of 40-3-2 soybean[2], the applicant has provided additional information. Germany identified however further questions for clarification, which were agreed by the Panel. In addition, the Panel identified some additional questions on the environmental risk assessment to be sent to the applicant.

- 59122xNK603 maize (application UK-2005-20): questions to the applicant for additional information on the food/feed safety of 59122xNK603 maize were identified by the Panel.

- 59122x1507x NK603 maize (application UK-2005-21): questions to the applicant for additional information on the food/feed safety of 59122x1507x NK603 maize were identified by the Panel.

In case additional information is requested to the applicant, the assessment procedure is kept on hold (the clock is stopped).

The issue was raised about the design of field trials which should be done in more than one location and over more than one season and regarding whether the locations should be the same from season to season, or may differ between seasons. The issue will be further considered in the self tasking working group on statistics.
The use of a negative segregant as the only comparator in the field trials was also discussed. An appropriate non-GM comparator should always be included in the compositional analysis.

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

7.1. Applications under Regulation (EC) No 1829/2003

EFSA received, via the Netherlands, one new application (NL-2007-47: 305423 x 40-3-2 soybean) within the framework of Regulation (EC) No 1829/2003 for an overall opinion including the scientific opinion on the GMO for import and processing, food and feed use.

Nominated risk assessment bodies of the Member States and national competent authorities within the meaning of Directive 2001/18/EC as foreseen by Articles 6 (4) and 18 (4) of Regulation (EC) No 1829/2003 will be consulted by EFSA once the above mentioned application is valid. These

[2] See agenda item 6.2 of the minutes of the 30th plenary meeting (http://www.efsa.europa.eu/EFSA/efsa_locale-1178620753812_1178620775239.htm).

comments will be considered during the scientific risk assessment of the application by the EFSA GMO Panel.

The summary of this application, as well as the information on its current status can be found on the following website:
http://www.efsa.eu.int/science/gmo/gm_ff_applications/catindex_en.html.

7.2. Applications under Directive 2001/18/EC

EFSA received from the European Commission a request for a scientific opinion on Carnation Moonaqua 123.8.12 from Florigene Limited introduced under Directive 2001/18/EC for import of the GM line (NL-2007-47). In particular, EFSA is requested to take account of the objections raised by the Competent Authorities of the Member States in the context of Directive 2001/18/EC.

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

8.1. Statistical considerations in the safety evaluation of GMOs

A meeting was organised on 14 September 2007 between the working group (WG) on Statistics and some applicants in order to discuss and gain access to workable datasets of GMO applications.

8.2. Allergenicity assessment of GM foods

A WG meeting took place on 24 September 2007 to further elaborate on the different contributions of the sub-WGs, including chapters on structural aspects, bioinformatics and *in vitro* analysis for the assessment of potential allergenicity of GM foods. The WG also discussed the issue of adjuvanticity following comments from Norway on the possible adjuvant effect of Cry proteins within the framework of Regulation 1829/2003-applications and the corresponding opinions of the GMO Panel[3].

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

A first draft of the report for the assessment of GM plants used for non-food/feed purposes was presented to the Panel. The report will be updated following the discussions held and a revised version will be presented at the next plenary meeting.

9. FEEDBACK FROM EFSA AND THE SCIENTIFIC COMMITTEE

The Panel was informed about the outcome of the 26th Plenary meeting of the Scientific Committee held on 17-18 September 2007. The minutes of this meeting can be found at: http://www.efsa.europa.eu/EFSA/efsa_locale-1178620753812_1178637648320.htm.

[3] See item 8.2 of the minutes of the 35th plenary meeting (http://www.efsa.europa.eu/EFSA/efsa_locale-1178620753812_1178636420918.htm).

10. FEEDBACK FROM THE COMMISSION

The Commission representative updated the Panel on ongoing discussions between the Commission and US authorities in the context of the WTO dispute concerning GMOs. EFSA has assisted the Commission in one of those meetings in explaining the GMO authorization procedure to the US. The US authorities have indicated that the scientific risk assessments done by EFSA are not posing a problem and will not be used against the EU in future WTO litigation.

The Panel was also informed about the outcome of the 7th Codex ad hoc Intergovernmental Task Force on Foods derived from Biotechnology held from 24 to 28 September 2007 in Chiba, Japan. Christer Andersson has been assisting the Commission as GMO Panel member on behalf of EFSA. The Task Force agreed on the draft guidelines related to the food safety assessment of foods derived from r-DNA animals, as well as on two annexes to the available guideline on r-DNA plants, considering r-DNA plants modified for nutritional or health benefits and the food safety assessment in situations of low-level presence of r-DNA plant material in food, respectively.

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 authorization, 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

The Panel was informed about a letter from Greenpeace (21 August 2007) regarding the application UK-2006-34 (GM maize 3272). The letter will be forwarded to the working groups on molecular characterisation and food/feed safety when this application will be considered.

The Panel was informed about a letter from EuropaBio related to the EFSA Guidance Document of the GMO Panel for the risk assessment of genetically modified plants containing stacked transformation events. EuropaBio will be asked to send their specific comments in writing regarding their request for clarification of the requirements given in the guidance document.

The Panel has drafted a document on the environmental risk assessment of GM herbicide tolerant plants and the interplay between Directive 2001/18/EC and Directive 91/414/EC in order to propose an approach to be followed in the frame of the environmental risk assessment of GM herbicide tolerant crops, specifically in relation to assessing the environmental impacts of the specific cultivation aspects (i.e. the use of herbicides) associated with these crops. The Commission will be asked for their comments before the document will go out for public consultation.

A draft document on molecular characterisation for transgenic plants from the joint OECD Working Group for Harmonisation in Biotechnology and the Task Force for the Safety of Novel Foods and Feeds was circulated to the Panel and will be further considered by the working group on molecular characterisation of the Panel.