MINUTES OF THE 32ND PLENARY MEETING OF THE SCIENTIFIC PANEL ON GENETICALLY MODIFIED ORGANISMS HELD ON 22-23 MARCH 2007 (ADOPTED ON 16 MAY 2007)

AGENDA

PARTICIPANTS

GMO Panel:
Hans Christer Andersson, Salvatore Arpaia, Detlef Bartsch[1], Josep Casacuberta, Howard Davies, Marc De Loose, Lieve Herman, Sirpa Kärenlampi (Vice-Chair), Jozsef Kiss, Ilona Kryspin-Sorensen, Harry Kuiper (Chair), Ingolf Nes, Nickolas Panopoulos, Joe Perry, Annette Pöting, Joachim Schiemann, Willem Seinen[1], 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
Executive Directorate: Catherine Geslain-Lanéelle[2].

European Commission:
Aurélie André (DG ENV), Sabine Pelsser, Marco Valletta and Michael Walsh (DG SANCO).

APOLOGIES

GMO Panel:
Niels Bohse Hendriksen.

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1. WELCOME AND APOLOGIES FOR ABSENCE

The Chair opened the meeting and welcomed all. Apologies for absence were received from Niels Bohse Hendriksen.

2. ADOPTION OF THE AGENDA

In addition to the proposed agenda, the draft guidance document on stacked events was placed on the agenda for possible adoption.

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. Regarding the 59122 maize application (see item

[1] Only present on 22 March.
[2] Only present for agenda point 13.

5.1), one expert[3] declared that its institute by which he is involved conducted biosafety studies on 59122 maize. This expert will therefore abstain from voting on this opinion.

As regards the new applications (see item 9.2), some members[4] indicated that they in the future may be to some extent involved in the safety assessment process of these applications at national level and provided a written declaration. It was decided from these declarations that there was no conflict of interest and that involvement in the national safety assessment process did not compromise the assessment of applications by EFSA.

4. ADOPTION OF THE MINUTES OF THE 31ST PLENARY MEETING HELD ON 31 JANUARY – 1 FEBRUARY 2007

The minutes of the 31st plenary meeting (31 January - 1 February 2007) were adopted as proposed and will be published at:

http://www.efsa.europa.eu/en/science/gmo/gmo_meetings/gmo_31st_meeting.html.

5. DISCUSSION AND POSSIBLE ADOPTION OF OPINIONS ON:

5.1. 59122 Maize (Application NL-2005-12 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 the genetically modified maize 59122 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 of maize 59122 does not raise safety concerns, and that sufficient evidence for the stability of the insert structure was provided.

[3] Jozsef Kiss
[4] Detlef Bartsch

Comparative analysis has shown that maize 59122 is compositionally and agronomically equivalent to conventional maize lines, except for the introduced transgenic traits. The risk assessment included an analysis of data from analytical studies, bioinformatics, and *in vitro* and *in vivo* studies. The Panel concluded that the maize 59122 is as safe as its non-GM counterparts and that the overall allergenicity of the whole plant is not changed.

The application EFSA-GMO-NL-2005-12 concerns food and feed uses, import and processing of maize 59122. There is therefore no requirement for scientific information on possible environmental effects associated with the cultivation of maize 59122. There are no indications of increased likelihood of establishment or survival of feral maize plants in case of accidental release into the environment of 59122 seeds during transportation and processing. Also, the low levels of environmental exposure through other routes indicate that the risk to target and non-target organisms is likely to be extremely low. The scope of the monitoring plan provided by the applicant is in line with the intended uses of maize 59122.

In conclusion, the Panel considers that information available for maize 59122 addresses the comments raised by the Member States and considers it unlikely that maize 59122 will have any adverse effect on human and animal health or on the environment in the context of its intended uses.

Adoption

The opinion was adopted unanimously by the Panel. The opinion and the table containing the responses of the Panel to MS comments can be found on the EFSA website at: http://www.efsa.europa.eu/en/science/gmo/gmo_opinions/gmo_maize59122.html.

5.2. A7204-12 Soybean (Application NL-2005-18 under Regulation (EC) 1829/2003)

The molecular characterisation and environmental risk assessment parts of the scientific opinion were agreed by the Panel. The food/feed safety part was not yet finalised and the adoption of the opinion was therefore deferred to a next plenary meeting.

5.3. Rovabio™ PHY AP/LC (3-phytase) (Application under Regulation (EC) 1831/2003)

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, user and consumer, and the environment of the product RovabioTM PHY AP/LC, which is a preparation of 3-phytase produced by genetically modified microorganism *Penicillium funiculosum* 4.05b (CBS 111433), 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 introduced genes do not trigger any particular safety concerns in terms of the presence of toxins or antibiotics. The final enzyme

preparation contains no cultivable producer organisms, no antibacterial 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 of the co-opinion will be adopted by the FEEDAP Panel, it will be published on the EFSA website at:

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

5.4. Guidance document for the risk assessment of GM plants containing stacked transformation events

The draft guidance for the risk assessment of GM plants containing stacked transformation events was presented to the Panel. Although there was overall agreement on the risk assessment approach as outlined in the document, the document needs some substantial editorial changes before final adoption. The adoption of the opinion was therefore referred to the next plenary meeting.

6. ANTIBIOTIC RESISTANCE MARKER GENES (*NPT*II)

Introduction

Following the request from the Commission to the EMEA[5] and the subsequent Commission request to EFSA (letter dated 2 March, 2007), the Panel has drafted a statement on the safe use of the *npt*II antibiotic resistance marker gene in GM plants.

In its response to the Commission, the EMEA concluded that neomycin and kanamycin, for which *npt*II may confer resistance, are of importance for veterinary and human use and that their current and potential future use cannot be classified as of no, or only minor, therapeutic relevance.

The Commission has requested EFSA to consider the information provided by the EMEA and to indicate the potential consequences of the EMEA's conclusions on the safety assessment of the *npt*II gene and, where applicable, on the specific assessments of GMOs and derived food and feed.

Discussion and adoption

The Panel agrees with the EMEA that the preservation of the therapeutic potential of the aminoglycoside group of antibiotics is important. The Panel is also of the opinion that the therapeutic effect of these antibiotics will not be compromised by the presence of the *npt*II gene in GM plants, given the extremely low probability of gene transfer from plants to bacteria and its subsequent expression. Furthermore, the Panel considers it very unlikely that the presence of the *npt*II gene in GM plants will change the existing widespread prevalence of this antibiotic resistance gene in bacterial sources in the environment. The Panel also points to evidence which indicates that integration of the *npt*II gene would only be one of many mechanisms by which bacteria could become resistant to aminoglycosides such as kanamycin.

[5] See point 14 of the minutes of 31st plenary meeting (http://www.efsa.europa.eu/en/science/gmo/gmo_meetings/gmo_31st_meeting.html).

Therefore, the Panel reiterates its earlier conclusions (opinion on antibiotic resistance marker genes[6]) that the use of the *npt*II gene as selectable marker in GM plants (and derived food or feed) does not pose a risk to human or animal health or to the environment. The Panel also confirms earlier safety assessments of GM plants and derived food/feed comprising the *npt*II gene.

The statement can be found on the EFSA website at:
http://www.efsa.europa.eu/en/science/gmo/statements0/npt2.html.

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

No update on other applications was provided because of time constraints.

8. OVERVIEW OF BT TOXINS CURRENTLY AVAILABLE FOR PEST CONTROL

Neil Crickmore, from the University of Sussex and chair of the European sponsored project COST 862 (Bacterial toxins for insect control), was invited to the Plenary meeting to give a presentation on Bt toxins for pest control.

The presentation provided an overview of Bt toxins, their classification, mechanism and specificity of action, and safety considerations. The following Bt toxins were presented: three-domain toxins, Mtx group, Bin group (including Cry34 / Cry35), Cry48 / Cry 49, Cry6, Cry22, Cry45, Parasporins, Vip toxins (including Sip1A), Cyt toxins and Recombinant toxins.

The update on Bt toxins was considered very useful by the Panel in view of the assessment of GM plants that express some of the less known CRY toxins.

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

9.1. Guidance on environmental and human health risk assessment of GM animals

This agenda item was deferred to next plenary meeting because of time constraints.

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

EFSA received, via the Netherlands, France and the UK, 7 new applications (NL-2007-37 maize MON 89034, NL-2007-38 maize MON 89034 x NK 603, NL-2007-39 maize MON 89034 x MON 88017, FR-2007-40 dried killed bacterial biomass PL73 Escherichia coli (LYS), UK-2007-41 cotton MON88913, UK-2007-42 cotton MON 88913 x MON 15985, UK-2007-43 soybean 356043) within the framework of Regulation (EC) No 1829/2003 for an overall opinion including the scientific opinion on the different GMOs 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 applications are valid. These

[6] http://www.efsa.europa.eu/en/science/gmo/gmo_opinions/384.html

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

The summaries of these applications, as well as the information on their current status can be found on the following website:
http://www.efsa.eu.int/science/gmo/gm_ff_applications/catindex_en.html.

10. RECENT PUBLICATION ON MON 863 MAIZE

The European Commission has requested that EFSA examine the recently published CRIIGEN study on the statistical analysis of the GM maize MON 863 toxicology data, to identify any potential consequences for EFSA's earlier assessment and its opinion[7] and statement[8] on MON 863 as regards food and feed safety.

The Panel considered this publication and the Panel saw no immediate need to change its previous assessments with respect to the safety of this maize. However, EFSA will initiate its own statistical work and consult Member States via the EFSA Advisory Forum to ascertain whether there is any further relevant data that may also help its response to the Commission. Based on the statistical study and input from Member States and the GMO Panel, EFSA will then give its response to the Commission.

11. OUTCOME SCIENTIFIC HEARING WITH APPLICANTS

The scientific hearing with applicants took place on 21 March 2007 and has been organised by EFSA and the Panel in order to be informed about forthcoming developments in the area of plant biotechnology which may lead to further issues to be addressed in risk assessments (e.g. guidance documents, self tasking activities).

The current approach for the risk assessment of GM plants as outlined in the EFSA GM plant guidance document[3] appears to be applicable to products that are expected to be submitted within the next 5 years. Some further questions might need to be addressed for plants with modifications influencing, more extensively, metabolic pathways. Profiling technologies (transcriptomics, proteomics, metabolomics) could offer supplementary approaches to address possible unintended effects in these cases, both during the experimental and product development phase, and possibly in the final risk assessment process.

The minutes of this hearing and the presentations of the applicants will be published on the EFSA website at:
http://www.efsa.europa.eu/en/stakeholders_efsa/technical_meetings/gmo_scientific_hearings.html.

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

[7] http://www.efsa.europa.eu/en/science/gmo/gmo_opinions/381.html and http://www.efsa.europa.eu/en/science/gmo/gmo_opinions/383.html

[8] http://www.efsa.europa.eu/en/science/gmo/statements0/statements.html

This agenda item was deferred to a next plenary meeting because of time constraints.

13. FEEDBACK FROM EFSA AND THE SCIENTIFIC COMMITTEE

The 23rd Plenary meeting of the Scientific Committee was held on 15-16 February 2007. The minutes of this meeting will be published at: http://www.efsa.europa.eu/en/science/sc_commitee/sc_meetings/23rd_sc_meeting.html.

The Executive Director of EFSA, Catherine Geslain-Lanéelle, discussed with the Panel some ways of handling the urgent requests that have been received recently. She is aware that the workload of the Panel is not always exclusively triggered by scientific needs from the European Commission and that a strict prioritization of the work and division of tasks between the GMO Panel, the EFSA staff and hierarchy will be considered.

14. DATES OF FUTURE MEETINGS

The next plenary meeting will be held on 16 May 2007 in Ljubljana, Slovenia, back to back to the 2nd Meeting of the European Advisory Committees on Biosafety on the field of the deliberate release of GMOs.

15. ANY OTHER BUSINESS

No other business was discussed.