MINUTES OF THE 34TH PLENARY MEETING OF THE SCIENTIFIC PANEL ON GENETICALLY MODIFIED ORGANISMS HELD ON 4-5 JULY 2007 IN PARMA, ITALY (ADOPTED ON 12 SEPTEMBER 2007)

AGENDA

PARTICIPANTS

GMO Panel:
Hans Christer Andersson, Salvatore Arpaia, Detlef Bartsch[1], Howard Davies, Niels Bohse Hendriksen, Lieve Herman, Sirpa Kärenlampi, Jozsef Kiss, Ilona Kryspin-Sorensen, Harry Kuiper (Chair), Ingolf Nes, Joe Perry, Annette Pöting, Joachim Schiemann, Willem Seinen and Jeremy Sweet.

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:
Bernadette Murray[2] (DG ENV), Sébastien Goux and Michael Walsh (DG SANCO).

APOLOGIES

GMO Panel:
Josep Casacuberta, Marc De Loose, Nickolas Panopoulos 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 asked to update their annual declarations of interest that are published on the EFSA website[3], based on the new template as prepared by EFSA.

In addition, Panel members were invited to declare possible interests on topics included on the agenda. In the case Panel members have an interest to declare, they will be asked to fill in a specific declaration of interest, which will be reported in the minutes of the plenary meetings as has been done so far.

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[1] Present only on 4 July
[2] Present only on 5 July
[3] http://www.efsa.europa.eu/en/science/gmo/gmo_members.html

4. ADOPTION OF THE MINUTES OF THE 33RD PLENARY MEETING HELD ON 16 MAY 2007

The minutes of the 33rd plenary meeting (16 May 2007) were adopted as proposed and will be published at:

http://www.efsa.europa.eu/en/science/gmo/gmo_meetings/gmo_33rd_meeting.html.

5. DISCUSSION AND POSSIBLE ADOPTION OF OPINIONS ON:

5.1. A7204-12 Soybean (Application NL-2005-18 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 soybean A7204-12 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 A2704-12 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 soybean A2704-12 is compositionally and agronomically equivalent to conventional soybean lines, 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 GMO Panel concluded that the soybean A2704-12 is as safe as its non GM counterpart and that the overall allergenicity of the whole plant is not changed.

The application 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 soybean A2704-12. Considering the scope of the application, not for cultivation, the Panel is of the opinion that the likelihood of the spread and establishment of soybean A2704-12 is very low and that unintended environmental effects due to this soybean will be no different from that of conventional soybean varieties. The scope of the monitoring plan provided by the applicant and the reporting intervals are in line with the intended uses of soybean A2704-12 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 soybean A2704-12, it is unlikely that soybean A2704-12 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 can be found on the EFSA website at:

http://www.efsa.europa.eu/en/science/gmo/gmo_opinions/ej524_soybean.html.

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

Ongoing applications

- LLRice62 rice (application UK/2004/04): the Panel identified further questions to the applicant with respect to the molecular characterization of LLRice62.

- 59122 Maize (application NL-2005-23): EFSA met COGEM and the Dutch Competent Authority performing the initial environmental risk assessment of the 59122 maize application to discuss possible questions for additional information to be sent to the applicant.

- LY038 Maize (application NL-2006-31): questions to applicant for additional information on the food/feed safety of LY038 maize were identified by the Panel. In addition, the answer from the applicant to the request from the Panel for clarification of the molecular characterisation of LY038 was not considered satisfactory.

- T45 Oilseed rape (application UK-2005-25): the Panel identified questions to the applicant for further clarification of the molecular characterisation of T45 Oilseed rape.

- MON88017 maize (application CZ-2005-27): the Panel identified questions to the applicant with respect to the molecular characterisation of MON88017 maize.

- Dried killed bacterial biomass applications (applications FR-2007-40 and FR-2007-44) will be assessed in cooperation with the FEEDAP Panel. The GMO Panel will assess the genetic modification and environmental aspects of the applications, whereas the FEEDAP Panel will look at the nutritional and toxicity aspects of the feed.

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

7. STATEMENT ON THE ANALYSIS OF DATA FROM A 90-DAY RAT FEEDING STUDY WITH MON 863 MAIZE

Following the request from the European Commission to examine the recently published CRIIGEN study on the statistical analysis of the GM maize MON 863 toxicology data (see items 10 and 7 of

the minutes of the 32nd plenary meeting[4] and of the 33rd plenary meeting[5] respectively), the Panel has adopted a statement on 25 June 2007 by written procedure.

The Panel has carefully considered the results of the statistical re-analysis of the 90-day rat feeding study with MON 863 maize in relation to the previous evaluations[6,7].

The Panel has considered the biological relevance of all statistically significant differences in test parameters. Observed differences in test parameters of exposed male and female rats were in general neither dose-related nor sex-dependent and were therefore considered as isolated phenomena occurring by chance. Furthermore the Panel has taken the natural variability of the test parameters into account. Given the fact that deviations in test parameters were relatively small and for the greatest part within natural variation ranges, the Panel did not consider these effects as biologically relevant.

In the absence of any indications that the observed differences in test parameters are indicative of adverse effects, the Panel does not consider that the publication by Séralini et al.[8] raises new issues which are toxicologically relevant. Therefore, the Panel sees no reason to revise its previous opinion that the MON 863 maize would not have an adverse effect on human and animal health or the environment in the context of its proposed use.

The Panel is aware of the fact that different approaches are applied in the statistical analysis of data obtained from animal experiments and has signaled the need for a harmonised approach in this area. A working group of the Panel is currently addressing this issue.

The full statement can be found at:
http://www.efsa.europa.eu/en/science/gmo/statements0/gmo_statement_mon863_ratfeeding.html

The EFSA report that was provided by an EFSA Task Force to advise the Panel on this matter and which provides a detailed statistical review is published on the following website:
http://www.efsa.europa.eu/en/science/scientific_reports/statistical_analyses_MON863.html

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

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

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[4] http://www.efsa.europa.eu/en/science/gmo/gmo_meetings/gmo_32nd_meeting.html

[5] http://www.efsa.europa.eu/en/science/gmo/gmo_meetings/gmo_33rd_meeting.html

[6] Opinions of the GMO Panel related to the placing on the market of insect-protected genetically modified maize MON 863 and MON 863 x MON 810.
http://www.efsa.europa.eu/etc/medialib/efsa/science/gmo/gmo_opinions/381.Par.0001.File.dat/opinion_gmo_06_en1.pdf &
http://www.efsa.europa.eu/etc/medialib/efsa/science/gmo/gmo_opinions/383.Par.0001.File.dat/opinion_gmo_07_en1.pdf

[7] Statement of the GMO Panel on the evaluation of the 13-week rat feeding study on MON 863 maize, submitted by the German authorities to the European Commission.
http://www.efsa.europa.eu/etc/medialib/efsa/science/gmo/statements/666.Par.0001.File.dat/sr_gmo01_statement_study_MON 863_en1.pdf

[8] Séralini, G.E., Cellier, D., de Vendomois, J.,S., 2007. New analysis of a rat feeding study with a genetically modified maize reveals signs of hepatorenal toxicity. Arch. Environ. Contam. Toxicol., 52, 596-602.

EFSA received, via the Netherlands, one new application (NL-2007-45: 305423 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 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.

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

EFSA received from the European Commission three requests for scientific opinions on GMO-derived feed enzymes (L-Valine for all species (EFSA-Q-2007-103), Econase XT L/P (beta-1,4-xylanase) for chickens and turkeys for fattening, chickens reared for laying, turkeys reared for breeding and piglets (EFSA-Q-2007-120) and Ronozyme NP (6-phytase) for chickens for fattening (EFSA-Q-2007-133)) within the framework of Regulation (EC) 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 the FEEDAP Panel will perform the risk assessment of the feed additive.

9. OUTCOME OF EFSA SCIENTIFIC COLLOQUIUM ON THE ENVIRONMENTAL RISK ASSESSMENT OF GM PLANTS HELD ON 20-21 JUNE IN TABIANO, ITALY

On 20 and 21 June, EFSA held a two day Scientific Colloquium in Tabiano, Province of Parma on the Environmental Risk Assessment (ERA) of GM plants. Some 100 scientists and stakeholders from both EU and non-EU countries discussed approaches to environmental risk assessment in the light of current scientific thinking, focusing on issues such as environmental fitness, effects on non-target organisms, long-term and large scale environmental effects, broader environmental considerations and the assessment of risk versus environmental benefit.

Participants agreed on the current case-by-case approach to ERA, as outlined in EFSA's guidance, and that EFSA's risk assessment work on ERA was at the forefront of developments in this area. Experts at the colloquium argued that more specific guidance may be needed for the assessment of the potential impact on non-target organisms in terms of design and statistical power of testing. Modelling may be a useful tool to predict potential effects that GM plants might have over time and when cultivated on a larger scale in Europe. In addition, post-market environmental monitoring will play an important role for determining long-term effects of GM plants and for testing model predictions.

The presentations given and the summary report will be published on the EFSA website at:
http://www.efsa.europa.eu/en/science/colloquium_series/Colloquium_8_gmo.html.

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

10.1. Animal feeding trials

The working group on animal feeding trials aims at finalising its report in order to present it to the GMO Panel at their September plenary meeting for possible adoption.

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

A sixth working group meeting was held on 31 May 2007 during which the draft report was discussed and outstanding issues identified. Specific case studies of GM plants used for non-food/feed purposes will be further elaborated by a sub-working group meeting scheduled at 18 July 2007.

10.3. Statistical considerations in the safety evaluation of GMOs

A fifth working group meeting took place on 5 June 2007. A preliminary report of the working group will be presented at the next GMO Plenary meeting.

11. GMO CALLS FOR ARTICLE 36 PROPOSALS: CRY PROTEINS AND IMPACT OF GM HERBICIDE TOLERANT PLANTS ON NON-TARGET ORGANISMS

Two calls for proposals for outsourcing a task to a Member State institution within the framework of Article 36 of EFSA's founding Regulation (EC) 178/2002 have been published on the EFSA website (http://www.efsa.europa.eu/en/about_efsa/cooperation/call_for_proposal.html). The purpose of these assignments is to provide EFSA with a written scientific report on Cry proteins with a focus on their safety for human and animal health and the environment and with a report on the state-of-the-art on the impact of GM herbicide tolerant plants on non-target organisms. The deadline for submitting proposals is 20 August 2007.

12. FEEDBACK FROM EFSA AND THE SCIENTIFIC COMMITTEE

A working group of the Scientific Committee has been established to assess the implications of animal cloning on food safety, animal health and welfare and environment.

13. FEEDBACK FROM THE COMMISSION

The Commission 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.

14. DATES OF FUTURE MEETINGS

The following GMO Panel plenary meetings have been scheduled in the fall of 2007: 12-13 September (Parma); 30 - 31 October (Parma); 22 - 23 November (Brussels, back to back to the EFSA's 5th anniversary Scientific Forum of 20-21 November); 18-19 December (Parma).

A proposal for plenary meetings in 2008 was also discussed.

15. ANY OTHER BUSINESS

The Commission has provisionally inquired EFSA about the view of the Panel on a letter provided by Germany in support of the invocation of a safeguard clause for cultivation of MON 810 maize according to Article 23 of Directive 2001/18/EC. The Panel is of the opinion that the letter provided by Germany does not comprise i) new or additional scientific information that will impact the previous scientific evaluation carried out on MON810 maize; ii) new scientific publication that the GMO Panel has not previously considered in its former scientific opinions/statements. The Panel will assess the monitoring plan of MON810 maize in the context of the submitted applications for renewal of MON810 maize for food, feed and cultivation purposes.

EFSA received via the Commission a letter from the Competent Authority of Austria with a statement from its national expert on antibiotic resistant marker (ARM) genes. This letter refers to the "Statement of the Scientific Panel on Genetically Modified Organisms on the safe use of the nptII antibiotic resistance marker gene in genetically modified plants[9]". The above mentioned Austrian statement agrees with the conclusion of the Panel that the probability of functional gene transfer from plants into microorganisms is extremely low. In its statement on the safe use of the *npt*II ARM gene in GM plants, the Panel also concluded that the therapeutic effect of the aminoglycoside group of antibiotics will not be compromised by the presence of the *npt*II gene in GM plants. In the Austrian statement concern was expressed that "a single successful transfer is enough to build up a founder generation, which is able to spread the newly acquired resistance vertically to an offspring generation via clonal expansion or horizontally via conjugation and transduction". The Panel discussed this issue and noted that the *npt*II gene is already present in environmental and clinical isolates. Therefore, the Panel confirms that is very unlikely that the presence of the *npt*II gene in GM plants will add to the existing prevalence of this antibiotic resistance gene in bacterial sources. This conclusion of the GMO panel has been previously supported by the Austrian Bundesministerium für Gesundheit und Frauen who recommended to the Austrian Competent Authorities in a document by Mag. Markus Wögerbauer entitled "Risikoabschätzung von Resistenzmarkergenen in transgenen Pflanzen" (English Summary) (2006, ISBN 3-900019-64-9) that "no indications in the recent literature can be found for a scientifically based argument in favour of a strict rejection of transgenic plants which contain group I antibiotic resistance marker genes" (The *npt*II gene is included in group I.). This document comprised a risk assessment of ARM genes on the basis of the relevant scientific literature available until November 2005. The Panel noticed that in the above mentioned Austrian statement other additional publications have been discussed as well. The Panel is of the opinion that the information provided does not change the conclusions of its earlier statement.

The Panel was informed by the Commission about a press statement from Greenpeace, based on a new study of CRIIGEN that presumes the possible toxicity of NK603 maize. The information that is being circulated via the internet is not providing any new scientific evidence with respect to the safety of NK603 maize. In addition, for this case, contrary to MON863 maize, there is no claim made through a peer reviewed scientific publication. From EFSA's extensive analysis on the MON863 data (see item 7 of these minutes) it can be concluded that statistical approaches are a tool to identify differences between a GMO and its comparator but that the most important issue is to assess the biological implications of any changes, as done in the assessment by the GMO Panel.

[9] Adopted on 22 March 2007 (http://www.efsa.europa.eu/EFSA/Statement/gmo_statement_nptII_.pdf)

The safety of a GMO is determined on the basis of the complete data package in accordance with the EFSA guidance. The detailed assessment of NK603 maize is described in the EFSA opinions on that maize[10].

The Panel was informed about an EFSA statement on the fate of recombinant DNA or protein in meat, milk or eggs of animals fed with GM feed, following a petition from Greenpeace to label food products (such as meat, milk and eggs) from animals that have been fed with genetically modified feed and a subsequent request from the Commission. The statement will be published at: http://www.efsa.europa.eu/EFSA/Statement/EFSA_statement_DNA_proteins_gastroint.pdf.

[10] Opinions of the GMO Panel on GM maize NK603, 1507 x NK603, NK603 x MON810, MON863 x MON810 x NK603 and MON863 x NK603 (http://www.efsa.europa.eu/en/science/gmo/gmo_opinions/176.html & http://www.efsa.europa.eu/en/science/gmo/gmo_opinions/1482.html & http://www.efsa.europa.eu/en/science/gmo/gmo_opinions/1284.html & http://www.efsa.europa.eu/en/science/gmo/gmo_opinions/1033.html & http://www.efsa.europa.eu/en/science/gmo/gmo_opinions/1032.html).