MINUTES OF THE 46TH PLENARY MEETING OF THE SCIENTIFIC PANEL ON GENETICALLY MODIFIED ORGANISMS HELD ON 3-4 DECEMBER 2008 IN PARMA, ITALY (ADOPTED ON 28 JANUARY 2009)

PARTICIPANTS

GMO Panel:

Hans Christer Andersson, Detlef Bartsch[1], Josep Casacuberta, Howard Davies, Patrick du Jardin, Niels Bohse Hendriksen, Lieve Herman, Sirpa Kärenlampi, Jozsef Kiss, Gijs Kleter, Ilona Kryspin-

[1] Only present on 3 December 2008

Sorensen, Harry Kuiper (Chair), Nickolas Panopoulos, Joe Perry, Annette Pöting, Joachim Schiemann, Jeremy Sweet and Jean-Michel Wal.

EFSA:
Jaime Aguilera, Per Bergman, Anna Christodoulidou, Yann Devos, Zoltán Divéki, Christina Ehlert, Antonio Fernández Dumont, Andrea Germini, Ana Gomes, Karine Lheureux, Yi Liu, Sylvie Mestdagh, Claudia Paoletti, Reinhilde Schoonjans, Elisabeth Waigmann, Mara Todeschi, Podevin Nancy, Claudia Parisi.

European Commission:
Sabine Pelsser[2] and Michael Walsh[3] (DG SANCO), Helen Clayton (DG ENV)

APOLOGIES

GMO Panel: Salvatore Arpaia, Ingolf Nes, Willem Seinen
European Commission: Sébastien Goux (DG SANCO), Yannis Karamitsios and Bernadette Murray (DG ENV)

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1. WELCOME AND APOLOGIES FOR ABSENCE

The Chair opened the meeting and welcomed all. Apologies for absence were received from three Panel members and two colleagues from DG SANCO and one colleague from DG ENV as mentioned above. Two colleagues from the Commission and one panel member partially attended the meeting as indicate above.

2. ADOPTION OF THE AGENDA

The agenda was adopted after adding three items under Any Other Business.

3. DECLARATION OF INTERESTS

Panel members were invited to declare possible interests on topics included on the agenda. Declarations have been registered through the standard form submitted by the Panel members. One Panel member, Annette Pöting, indicated that she was involved in the assessment of the Austrian study "Biological effects of transgenic maize NK603xMON810" at national level (see Any Other Business). Although this involvement at national level was regarded as no conflict of interest, the Panel Member abstained from voting for this agenda item.

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[2] Only present in the afternoon of 3 December 2008

[3] Only present in the morning of 3 December 2008

4. ADOPTION OF THE MINUTES OF THE 45TH PLENARY MEETING HELD ON 29-30 OCTOBER 2008

The minutes of the 45th Plenary meeting (29-30 October 2008) were adopted after some corrections were made and are published at:
http://www.efsa.europa.eu/EFSA/efsa_locale-1178620753812_1211902152917.htm

5. DISCUSSION AND POSSIBLE ADOPTION OF OPINIONS ON:

5.1. Natugrain TS (EFSA-Q-GMO-NL-2008-013 under Regulation (EC) No 1831/2003; FEEDAP-GMO co-opinion)

Introduction

Within the framework of an application in accordance with Article 4(1) of Regulation (EC) No 1831/2003 on additives for use in animal nutrition, EFSA has been requested by the European Commission to deliver a scientific opinion on the safety and efficacy of the product Natugrain® TS and Natugrain® TS L (endo-1,4-ß-xylanase and endo-1,4-ß-glucanase) as a feed additive within the category of zootechnical additives, functional group digestibility enhancer, for chickens, turkeys and ducks for fattening, laying hens and piglets.

Discussion

The GMO Panel has been asked to perform the assessment of the GM aspects of the microorganism used for the production of this feed enzyme. The FEEDAP Panel will assess all other parts of the feed enzyme application.

The additive Natugrain® TS is produced in two formulations, i.e. Natugrain® TS L (liquid) and Natugrain® TS (solid). Both formulations contain thermostable endo-1,4-ß-xylanase and thermostable endo-1,4-β-glucanase, both enzymes being produced by genetically modified strains of *Aspergillus niger*. The genes encoding these enzymes were each derived from a thermotolerant ascomycete fungus, *Talaromyces emersonii* and were cloned in multiple copies into production strains of *A. niger* to increase enzyme yield. The molecular characterisation of the genetic modification does not trigger any particular safety concerns. The final enzyme preparation contains no cultivable production organisms and the level of recombinant DNA is below the limit of detection of 100 ng DNA g^{-1} of the solid enzyme product and 17 ng DNA mL^{-1} of the liquid product.

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. Maize MON89034 and derived food and feed (EFSA-GMO-NL-2007-37 under Regulation (EC) No 1829/2003; EFSA-Q-2007-042)

Introduction

The GMO 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 MON89034 for food and feed uses and import and processing (EFSA-GMO-NL-2007-37).

The risk assessment was based on the information provided in the new application EFSA-GMO-NL-2007-37, additional information provided by the applicant and the scientific comments submitted by the Member States.

Insect-resistant Maize MON89034 was transformed by *Agrobacterium tumefaciens*-mediated gene transfer technology. Maize MON89034 contains the Cry1A.105 and the Cry2Ab2 expression cassettes (T-DNA I) but does not contain the *npt*II expression cassette (T-DNA II). The Cry1A.105 and the Cry2Ab2 expression cassettes confer resistance to certain insect pests.

The opinion of the GMO 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 opinion in accordance with Articles 6(5) and 18(5).

Discussion

The GMO Panel is of the opinion that the molecular characterisation provided for the maize transformation event MON89034 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 GMO Panel considers that the molecular characterisation does not indicate any safety concern. Comparative analysis has shown that maize MON89034 is compositionally and agronomically equivalent to conventional maize, except for the introduced transgenic traits. The risk assessment included an analysis of data from analytical studies, bioinformatic, and *in vitro* and *in vivo* studies. The GMO Panel concluded that maize MON89034 is as safe as its non-GM counterpart and that the overall allergenicity of the whole plant is not changed.
The application EFSA-GMO-NL-2007-37 concerns food and feed uses, import and processing of maize MON89034. There is therefore no requirement for scientific assessment of possible environmental effects associated with the cultivation of the GM maize. There are no indications of increased likelihood of establishment or survival of feral maize plants in case of accidental release into the environment of MON89034 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 post-market environmental monitoring plan provided by the applicant is in line with the intended uses of maize MON89034.

In conclusion, the GMO Panel considers that information available for maize MON89034 addresses the comments raised by the Member States and considers it unlikely that maize MON89034 will have any adverse effect on human and animal health or on the environment in the context of its intended uses.

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

Adoption

The opinion was adopted unanimously by the Panel. The scientific opinion is published on the following EFSA website: http://www.efsa.europa.eu/en/science/gmo/gmo_opinions.html

The overall opinion, including the table containing the responses of the Panel to Member States is published in the Register of Questions EFSA-Q-2007-042:

http://registerofquestions.efsa.europa.eu/roqFrontend/questionsList.jsf

6. DISCUSSION OF OPINION ON:

6.1. Safeguard clause invoked by Austria according to Article 23 of Directive 2001/18/EC in relation to maize MON 810 and T25 (EFSA-Q-2008-314)

Introduction

On 18 April 2008, EFSA was requested by the European Commission, under Article 29(1) and in accordance with Articles 22(5) and 22(5) (c) of Regulation (EC) No 178/2002, to assess*:*

> *"whether the information submitted by Austria comprises information affecting the environmental risk assessment of existing information on the basis of new scientific knowledge such that detailed grounds exist to consider that the above authorised GMOs, for the uses laid down in the corresponding consent, constitute a risk to the environment"*

The GMO Panel considered and assessed the written information provided by the Austrian authorities in support of their safeguard clause. On 2 December experts of the GMO Panel met the Austrian Delegation and scientists in a technical bilateral meeting at EFSA to discuss the scientific issues and to identify whether there is new scientific evidence which was not considered in the previous risk assessments of maize MON810 and T25.

Discussion

The GMO Panel has investigated the claims and report provided by Austria. In the Austrian report, the GMO Panel did not identify any new data or scientific information that would change the previous risk assessments conducted on maize MON810 and T25, which currently have marketing consent in the EU. In addition, the Austrian submission did not supply scientific evidence that the environment or ecology of Austria presents conditions that would require separate risk assessments from those conducted for other regions in the EU.

The GMO Panel concluded that maize MON810 and T25 are unlikely to have adverse effects on human and animal health or on the environment in the context of their proposed uses. The GMO Panel therefore reaffirmed its previous conclusions on the safety of maize MON810 and T25.

Having considered the information submitted by Austria and a broad range of scientific literature, the GMO Panel was of the opinion that there is no specific scientific evidence, in terms of risk to human and animal health and the environment, that would justify the invocation of the safeguard clause under Article 23 of Directive 2001/18/EC for the marketing of maize MON810 and T25 for its intended uses in Austria.

In conclusion, the GMO Panel found that the scientific evidence currently available does not sustain the arguments provided by Austria and that cultivation of maize MON810 and maize T25 is unlikely to have an adverse effect on human and animal health and the environment in Austria.

Adoption

The opinion was adopted unanimously by the Panel. The opinion can be found on the EFSA website at: http://www.efsa.europa.eu/EFSA/ScientificPanels/GMO/efsa_locale-1178620753812_GMOOpinions455.htm.

6.2. Mandate for a consolidated opinion on the use of antibiotic resistant marker (ARM) genes in genetically modified plants (EFSA-Q-2008-411)

On 21 May 2008, EFSA received the request by the European Commission (SANCO reference: D/510274) for a consolidated opinion on the use of ARM genes as marker genes in genetically modified plants.

Information relevant to the issue of ARM genes used as markers in genetically modified plants is currently under review within EFSA in collaboration with the European Medicines Agency (EMEA), the European Centre for Disease Prevention and Control (ECDC) and other invited experts. Such consolidated opinion requires additional technical discussions and the deadline to deliver the opinion has been extended until March 2009.

Progress of the work has been presented to the GMO Panel, as well as procedural aspects such as the establishment of a Joint Working Group between experts of the GMO and BIOHAZ Panel and the appointment of a new Chair (Prof. Dr. Silano, Chair of the EFSA Scientific Committee) and Secretary (Dr. Stef Bronzwaer, Deputy Head of Scientific Cooperation Unit, EFSA). A small Drafting Group (which includes the vice-Chair and a member of the EFSA GMO Panel and the Chair of the BIOHAZ Panel and an outside expert) will further work on the draft opinion. The work plan involves meetings of the Drafting Group in December and February, followed by consultation of the collaborating parties and a meeting of the Joint Working Group before the March Plenary meetings of the GMO and BIOHAZ Panels in which the draft opinion will be proposed for adoption.

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

7.1 Written adoption for maize 59122 x NK603 and derived food and feed (EFSA-GMO-UK-2005-20) (EFSA-Q-2005-247)

The GMO Panel adopted on 19 November 2008 by written procedure the opinion on the Application (EFSA-GMO-UK-2005-20) for authorization of the insect-resistant, glyphosate- and glufosinate-tolerant genetically modified 59122 x NK603 maize and all derived products for food and feed uses, import and processing but excluding cultivation (EFSA-Q-2005-247).

The opinion was adopted unanimously by the Panel. The scientific opinion is published on the following EFSA website: http://www.efsa.europa.eu/en/science/gmo/gmo_opinions.html

The overall opinion, including the table containing the responses of the Panel to Member States is published in the Register of Questions EFSA-Q-2005-247: http://registerofquestions.efsa.europa.eu/roqFrontend/questionsList.jsf

7.2 Ongoing applications

- Maize LY038 (EFSA-GMO-NL-2006-31; EFSA-Q-2006-018): the GMO Panel discussed the reply of the applicant and will finalize its risk assessment opinion.
- For the renewal dossier RX- 40-3-2 Soybean (EFSA-GMO-RX-40-3-2; EFSA-Q-2007-142) further clarification from the applicant and discussion are needed.

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

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

Application for authorisation of genetically modified maize MON89034 x 1507 x MON88017 x 59122 was received through the Competent Authorities of Czech Republic under Regulation (EC) No 1829/2003 (EFSA-GMO-CZ-2008-62) (EFSA-Q-2008-764). Competent Authorities of the Member States within the meaning of Directive 2001/18/EC will be consulted by EFSA as foreseen by Articles 6 (4) and 18 (4) of Regulation (EC) No 1829/2003, once the above mentioned applications is valid. On its own initiative EFSA has broadened this consultation also to Competent Authorities and other national risk assessment bodies of the Member States under Regulation (EC) No 1829/2003. The comments will be considered during the scientific evaluation by the GMO Panel of the risk assessment performed by the applicant.

The summary of the application EFSA-GMO-CZ-2008-62, as well as the information on the current status can be found through the following webpage leading to EFSA's Register of Questions: http://registerofquestions.efsa.europa.eu/roqFrontend/questionsList.jsf.

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

None

9. UPDATE ON SELF TASK ACTIVITIES AND GUIDANCE FOR GMO RISK ASSESSMENT

Update Guidance Document for the risk assessment of GM plants and derived food and feed

During the public consultation, comments were received on the updated EFSA Guidance Document. The comments regarding the molecular characterization, toxicology and nutrition are currently being addressed in the Molecular Characterisation and Food/Feed Working Groups of the GMO Panel. Comments on compositional analysis, stacks and statistics will be addressed later on. Comments on allergenicity and environmental issues will not be addressed at this stage, as relevant documentation is currently under preparation in self tasking or other activities of the GMO Panel.

The updated Guidance Document forms the basis for the establishment of a legal framework for the risk assessment of genetically modified plants and derived food and feed and is currently under discussion by the Member States. Staff of the GMO Unit of EFSA as well as experts from the GMO Panel will attend the meeting of the Standing Committee on the Food Chain and Animal Health (SCoFCAH) on 16 December 2008.

Update Guidance for the Environmental Risk Assessment of GM plants and derived food or feed (EFSA-Q-2008-262)

The Panel was informed about the progress of this mandate, the planned meeting, the timeframe and the scheduled meeting of 17 December 2008 with representatives of Competent Authorities of the Member States under Directive 2001/18/EC.

Self-tasking activity on Non-Target Organism (NTO) (EFSA-Q-2008-089)

The Panel was informed about the progress of the NTO working group and the meeting of November. Attention was paid to the regional characteristics which are covered in the section on receiving environments. The next meeting will be in Brussels on 16 December 2008.

Guidance for the risk assessment of GM animals (EFSA-Q-2008-069)

The Panel was updated on the progress for the broadened mandate on GM animals.

The EFSA Working Group on Food/Feed, Molecular Characterization and additional *ad hoc* experts will start activities on this topic early 2009

With regard to the Environmental part of the future EFSA Guidance for GM animals, several calls for tenders will be published, comprising GM fish, mammals, insects and birds. The call for fish was re-launched on 27 November 2008, with more pro-active advertising, as no offers have been received in response to the first call.

Self-tasking on Allergenicity (EFSA-Q-2005-125)

The Panel was informed about the work being in progress. Two sub-working group meetings have taken place in order to further elaborate the draft report. Special attention has been paid to the recommendations following each chapter.

10. FEEDBACK FROM EFSA AND THE SCIENTIFIC COMMITTEE

The Panel was informed that the document on "Guidance of the Scientific Committee on the Transparency in the Scientific Aspects of Risk Assessment carried out by EFSA. Part 2: General Principles" was endorsed for public consultation on 1 December 2008. The GMO Panel will be invited to submit comments via the online tool.

An internal consultation will be held on the document of the Scientific Committee "Draft opinion on the use of the Benchmark Dose Approach in Risk Assessment", before submitting the draft opinion to the Scientific Committee for possible adoption.

11. FEEDBACK FROM THE COMMISSION

DG SANCO informed that the European Commission adopted on 4 December 2008 a Decision authorising GM soybean MON89788, also known as "Roundup Ready 2" soybean, for import and processing and food and feed uses. The Commission adopted the decision following an application submitted by the company Monsanto and a favourable scientific assessment from EFSA, which addressed all safety concerns. EFSA concluded that there is no risk to human or animal health or to the environment. MON89788 soybean underwent the full authorisation procedure set out in the EU legislation. As the Member States failed to deliver a qualified-majority decision for or against this authorisation in the Standing Committee on the Food Chain and Animal Health (SCoFCAH), and then in the Council, the dossier was sent back to the Commission for decision. The authorisation is valid for 10 years, and any products produced from this GM soybean will be subject to the strict labelling and traceability rules of EU. For more information, see: http://ec.europa.eu/food/food/biotechnology/index_en.htm

12. DATES OF FUTURE MEETINGS

New plenary dates for 2010 will be proposed in January 2009.

13. ANY OTHER BUSINESS

GMO Panel deliberations on the Austrian report "Biological effects of transgenic maize NK603 x MON 810 fed in long term reproduction studies in mice"[4].

On 11 November 2008 the Austrian Federal Ministry of Health, Family and Youth released a research report on studies in mice, conducted to assess the impact of genetically modified maize NK603 x MON 810 on reproduction (Biological effects of transgenic maize NK603 x MON 810 fed in long term reproduction studies in mice, Dr. Alberta Velimirov, Dr. Claudia Binter, Univ. Prof. Dr. Jürgen Zentek).

The report includes three studies, a life-time study, a multigeneration study (MGS), and a reproductive assessment by continuous breeding study (RACB). According to the authors the life-time study showed no statistically significant differences in survival between mice fed with kernels of maize NK603 x MON 810 and the controls. They also reported that, in the MGS study, no significant differences in reproductive traits were found between mice fed with kernels of maize NK603 x MON 810 and the controls. In the RACB study, the authors used a modified protocol of the original RACB study developed at the U.S. National Toxicology Program (NTP) for the testing of chemicals. Male and female mice were housed as breeding pairs for approximately 20 weeks and allowed to produce litters continuously throughout the cohabitation period. The authors identified differences in reproductive parameters between mice fed with the GM maize and the controls. They reported that there were statistically significantly fewer pups born in the GM group in the 3rd and 4th delivery and fewer pups weaned in the 4th litter compared with the control group.

[4] These deliberations have been adopted at the 46th plenary meeting (3-4 December 2008) and were published shortly afterwards as adopted part of the minutes. The present minutes of the 46th plenary meeting replace that publication, without changes to its content.

The GMO Panel considered this report and came to the following conclusions.

Regarding the RACB study, the summary Table 59 contains calculation errors and inconsistencies in the treatment of the data regarding the 3rd and 4th litters. In addition, it seems that the authors have calculated the number of pups at birth per pair and not per delivering pair, which is standard practice. Also, there appears to be methodological deficiencies in the statistical analysis that seriously compromise the interpretation of the data. For the reasons stated above, individual data are required for a proper assessment. In addition, more detailed information regarding the breeding scheme is needed. In particular, it should be clarified whether, in the 3rd and 4th pairing, the same or different pairs failed to reproduce.

Information regarding the normal variation of the parameters examined in this study for the mouse strain used (historical control data) is required before any conclusion may be drawn on possible alterations in reproductive performance. In addition, further information on the estrous cycle and histopathological parameters including spermatogenesis, follicle and oocyte counts is essential for assessing the claims of reduced fertility.

The GMO Panel also notes that information on the genetic identity and characteristics of the tested materials is not sufficient.

On the basis of the data presented the GMO Panel is of the opinion that no conclusions can be drawn from the report.

Further to its above deliberations on the Austrian report, the GMO Panel would like to draw the attention to the recently published EFSA report on the safety and nutritional assessment of GM plants and derived food and feed (Food and Chemical Toxicology 46 (2008) S2-S70[5]) regarding the use of animal feeding trials for the evaluation of potential long term effects.

Proposal for a new self-tasking on stacks and choice of comparators

The Panel discussed and agreed that, although the use of negative segregant may provide some useful information, the risk assessment of a GM plant based exclusively on the comparison with a negative segregant is not sufficient to perform a proper safety evaluation. This has implications for several pending dossiers submitted to EFSA for which the clock is stopped. The Panel will establish a Working Group to discuss the choice of appropriate comparator(s) for different events. This Working Group will also provide further details on the approach to be taken when appropriate comparators are not available and, consequently, a comparative safety assessment is not possible.

Bilateral meeting with the Belgian and French delegations

Part of the next meeting of the Food/Feed Working Group on applications will be dedicated to a technical discussion with Belgian and French delegates on aspects of the risk assessment methodologies.

Amendment of the OECD protocol 408

[5] http://www.efsa.europa.eu/EFSA/efsa_locale-1178620753812_1178660555237.htm

The European Commission, being a member of OECD, was asked to submit an EFSA proposal to the OECD. This will be further discussed at the January Plenary meeting.

Adoptions through written procedure

The Panel discussed the practical and financial implications of adoption of Opinions through written procedure in case the legal deadline falls between two Plenary meetings. EFSA staff indicated that this procedure is only to be used when there is no other option for meeting the legal deadline.