MINUTES OF THE 47TH PLENARY MEETING OF THE SCIENTIFIC PANEL ON GENETICALLY MODIFIED ORGANISMS HELD ON 28-29 JANUARY 2009 IN PARMA, ITALY (ADOPTED ON 11 MARCH 2009)

PARTICIPANTS

GMO Panel:

Hans Christer Andersson, Arpaia Salvatore, Detlef Bartsch[1], Josep Casacuberta, Patrick du Jardin, Lieve Herman, Sirpa Kärenlampi, Jozsef Kiss, Gijs Kleter, Ilona Kryspin-Sorensen, , Harry Kuiper (Chair), Joe Perry, Annette Pöting, Joachim Schiemann[2], Willem Seinen, Jeremy Sweet and Jean-Michel Wal.

[1] Only present on 28 January 2009

[2] Only present as from the afternoon of 28 January 2009

EFSA:
Per Bergman, Anna Christodoulidou, Zoltán Divéki, Andrea Germini, Ana Gomes, Karine Lheureux, Sylvie Mestdagh, Claudia Paoletti, Reinhilde Schoonjans, Elisabeth Waigmann, Mara Todeschi, Nancy Podevin.

Spanish Competent Authority[3]*:*
Felix Ortego Alonso and Lucia Roda of the Spanish Competent Authority (Directive 2001/18/EC)

European Commission:
Sébastien Goux and Michael Walsh (DG SANCO); Helen Clayton, Ioana Ispas and Bernadette Murray (DG ENV)

APOLOGIES

GMO Panel: Howard Davies, Niels Bohse Hendriksen, Ingolf Nes, Nick Panopoulos
European Commission: Sabine Pelsser (DG SANCO)

---

1. WELCOME AND APOLOGIES FOR ABSENCE

The Chair opened the meeting and welcomed all. Apologies for absence were received from four Panel members and one colleague from DG SANCO 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. Declarations have been registered through the standard form submitted by the Panel members.

4. ADOPTION OF THE MINUTES OF THE 46TH PLENARY MEETING HELD ON 3-4 DECEMBER 2008

The minutes of the 46th Plenary meeting (3-4 December 2008) were adopted after some corrections were made and are published at:
http://www.efsa.europa.eu/EFSA/efsa_locale-1178620753812_1211902199319.htm

5. DISCUSSION AND POSSIBLE ADOPTION OF OPINIONS ON:

[3] Only present in the Morning of 29 January 2009

5.1. Maize Bt11 and derived food and feed (EFSA-GMO-RX-Bt11 under Regulation (EC) No 1829/2003; EFSA-Q-2007-146)

Introduction

The GMO Panel was requested in accordance with Articles 8(1)(b) and 20(1)(b) of Regulation (EC) No 1829/2003 to provide a scientific opinion for renewal of the authorisation for continued marketing of existing products produced from the genetically modified maize Bt11 for food and feed uses (EFSA-GMO-RX-Bt11).
The assessment presented was based on the information provided by the applicant in the renewal application EFSA-GMO-RX-Bt11 and on the additional information provided by the applicant on request of the Panel.
Maize Bt11 was developed to provide protection against specific lepidopteran pests. The maize also contains a gene providing tolerance to the herbicide glufosinate ammonium.
The opinion of the GMO Panel corresponds to the safety assessment report as referred to in Articles 6(4) and 18(4) of Regulation (EC) No 1829/2003 and will be part of the overall opinion in accordance with Articles 6(5) and 18(5).

Discussion

In addition to the information available in the original application and that was taken into account by the GMO Panel in its previous opinion (EFSA, 2005), the applicant provided updated information on the utilisation of maize Bt11 in Europe and an estimation of human and animal exposure to the newly expressed proteins.
The applicant also provided a report of the peer reviewed scientific literature on Bt11 that has become available since the previous opinion of the GMO Panel. The Panel also considered additional, recently published literature. An extensive survey has been made including not only maize Bt11 but also other GM events in which the Cry1Ab insecticidal protein has been inserted, *e.g.* Bt 176 and maize MON 810. According to the applicant, in maize Bt11, the first 615 amino acid residues of the full length Cry1Ab protein are expressed while a longer Cry1Ab protein is expressed in maize MON 810. The GMO Panel has taken into consideration all the published information while assessing the truncated newly expressed Cry1Ab protein in maize Bt11. The publications analysed pertained to compositional analysis, toxicology and allergenicity and nutritional equivalence.

The impacts of diets containing the GM material on performances of various target animals, e.g. broilers, calves, lactating cows, sheep, piglets and finishing pigs and fish, were analysed in feeding studies. The overall performances were similar in animals fed the GM crops as compared to those that received the non-GM counterpart. No intact Cry1Ab protein or gene was detected in tissues of target animals fed diets containing Bt11 maize.

In conclusion, new information from this updated literature review and from additional studies performed by the applicant does not prompt the Panel to change its previous opinion that Bt11 maize is as safe and as nutritious as the non-GM counterpart.

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 under EFSA-Q-2007-146:

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

5.2. Maize LY038 and derived food and feed (EFSA-GMO-NL-2006-31 under Regulation (EC) No 1829/2003; EFSA-Q-2006-018)

The GMO Panel was requested to carry out a scientific assessment of the genetically modified maize LY038 for food and feed uses and import and processing in accordance with Articles 6(6) and 18(6) of Regulation (EC) No 1829/2003 (EFSA-GMO-NL-2006-31).

The risk assessment was based on the information provided in the application EFSA-GMO-NL-2006-31, additional information provided by the applicant and the scientific comments submitted by the Member States.

Event LY038 was developed to produce a lysine-enriched maize by the introduction, of the *Corynebacterium glutamicum cordapA* gene encoding the dihydrodipicolinate synthase (cDHDPS). DHDPS is a major rate-limiting enzyme for lysine biosynthesis in plants and bacteria. Bacterial cDHDPS enzyme is less sensitive to lysine feedback inhibition than the corresponding plant enzyme (DHDPS) and therefore the overall lysine production is expected to be higher in LY038 than in the conventional counterpart. During the development of maize LY038, the Cre-*lox* recombination system was used to remove the *npt*II cassette located between *lox*P sites.

The application has been discussed with respect to the use of the negative segregant as comparator. The GMO Panel has decided to draft a new set of questions to the applicant.

6. DISCUSSION OF OPINION ON:

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

On 21 May 2008, the European Food Safety Authority (EFSA) received the request by the European Commission (DG SANCO and DG ENV 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 marker genes 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 was presented to the GMO Panel by Stef Bronzwaer (Deputy Head of Scientific Cooperation Unit, EFSA and Secretary of the Joint Working Group of experts from the GMO and the BIOHAZ Panels). A drafting group processed the contributions from the different

Panels and further elaborated the draft document, which has been sent to the BIOHAZ Panel and the GMO Panel for further consideration. The drafting group will meet on 12 February 2009 and the Joint Working Group on 23-24 February 2009, to finalise the document to be submitted for possible adoption at the plenary meetings of both Panels in March.

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

7.1 Ongoing applications

- **Maize MON810 (EFSA-GMO-RX-MON810 ; EFSA-Q-2007-153 including cultivation)** Two delegates of the Spanish Competent Authority gave a presentation on the report of the Environmental Risk Assessment for this application in accordance with Article 6.3(c) and 18.3 (c) or Regulation (EC) No 1829/2003. The Panel thanked the Spanish Competent Authority for the high quality report. The report of the Spanish Competent Authority will be included as an annex to the final opinion adopted by the Panel. The Panel identified questions to the applicant for additional information with respect to the environmental risk assessment; these questions will be sent out after further consultation.

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 H7-1 Roundup Ready® Sugar beet for food and feed uses and cultivation was received through Germany (EFSA-GMO-DE-2008-63) (EFSA-Q-2008-782).

Competent Authorities of the Member States 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. On its own initiative EFSA has broadened this consultation also to Member States National Competent Authorities under Regulation (EC) No 1829/2003 and other national risk assessment bodies. The comments will be considered during the scientific evaluation by the EFSA GMO Panel of the risk assessment performed by the applicant.

The summary of the application EFSA-GMO-DE-2008-63, 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

- Request for a scientific opinion on supplementary information about the enzyme preparation of trade name ECONASE XT L and ECONASE XT P (EFSA-Q-2008-775). This request is related to the application for Econase XT L and Econase XT P (endo-1, 4-beta-xylanase) for chickens and turkeys for fattening, chickens reared for laying, turkeys reared for breeding and piglets (weaned)

and as zootechnical additives (enzymes) that was received through Finland under Regulation (EC) No 1831/2003 (EFSA-Q-2007-120).

- Application for authorisation of the enzyme preparation FINASE EC (6-phytase) for chickens for fattening, chickens reared for laying, laying hens, turkeys for fattening, turkeys reared for breeding, piglets (weaned), fattening pigs, sows, ducks and other minor species (i.e., geese, quail, pigeons, pheasants and other game birds) (EFSA-Q-2008-378) (FEEDAP-GMO co-opinion).

The summary of the application, 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.

9. FEEDBACK FROM THE COMMISSION

Information on future activities concerning the GM plant Guidance (food/feed section)

The Panel was updated about the progress of the GM plant Guidance Document (food/feed section). The Commission and the Member States have met several times to discuss the future guidance on the basis of the draft EFSA updated Guidance Document with the public comments considered by the Commission. The text has been further developed in cooperation with the working groups on molecular characterization and food & feed. The revised version was sent to the Member States in January 2009, at the fourth meeting, and the Member States were satisfied with the process. EFSA will be formally consulted in about two weeks.

10. DATES OF FUTURE MEETINGS

Dates for Plenary meetings in 2010 were proposed to the Panel. Plenary meeting dates for 2010 have been scheduled:

27-28 January 2010
10-11 March 2010
28-29 April 2010
26-27 May 2010
30 June and 01 July 2010
08-09 September 2010
20-21 October 2010
01-02 December 2010

11. ANY OTHER BUSINESS

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.

With regard to the food/feed part of the future EFSA Guidance for GM animals, the draft guidance recently published by the US mainly focuses on procedural aspects, on molecular characterization and food/feed topics. The EFSA Working Group on food/feed has been scheduled for February 18.

With regard to the Environmental part of the future EFSA Guidance for GM animals, a call for tender has been published on GM fish with a new deadline for 23 January 2008. Three offers have been received and are currently being evaluated.

Bilateral meeting on Austrian Safeguard clause measure:

The Panel was informed about the progress for the organization of the bilateral meeting on Safeguard clause invoked by the Austrian Authorities on Maize MON863 and oilseed rapes GT73 and Ms8/Rf3. The Austrian delegation did not accept the invitation of the 10-11 February due to other obligations and March 10 will be proposed as a new date for this meeting.