MINUTES OF THE 29TH PLENARY MEETING OF THE SCIENTIFIC PANEL ON GENETICALLY MODIFIED ORGANISMS HELD ON 7-8 NOVEMBER 2006 (ADOPTED ON 5 DECEMBER 2006)

AGENDA

PARTICIPANTS

GMO Panel:

Hans Christer Andersson, Salvatore Arpaia, Detlef Bartsch, Howard Davies, Ralf Einspanier, Marc De Loose, Niels Bohse Hendriksen, Lieve Herman, Sirpa Kärenlampi (Vice-Chair)[1], Jozsef Kiss, Ilona Kryspin-Sorensen, Harry Kuiper[2] (Chair), Ingolf Nes, Joe Perry, Annette Pöting, Joachim Schiemann, Willem Seinen, Jeremy Sweet (Vice-Chair) and Jean-Michel Wal.

[1] Chair on 7 November 2006 am.

[2] Not present on 7 November 2006 am.

EFSA:
GMO Unit: David Carlander, Karine Lheureux, Sylvie Mestdagh, Suzy Renckens, Reinhilde Schoonjans, Ellen Van Haver.

European Commission:
Aurélie André (DG ENV)[3], Sébastien Goux (DG SANCO) and Michael Walsh (DG SANCO).

APOLOGIES

GMO Panel:
Josep Casacuberta.

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1. WELCOME AND APOLOGIES FOR ABSENCE

The Chair opened the meeting and welcomed all. Apologies for absence were received from Josep Casacuberta.

Nickolas Panopoulos was welcomed in particular as new Panel member. He introduced himself, focusing on his area of expertise. His biography can be found on the EFSA website: http://www.efsa.europa.eu/en/science/gmo/gmo_members.html.

2. ADOPTION OF THE AGENDA

The agenda was adopted as proposed.

3. DECLARATION OF INTERESTS

The new Panel member, Nickolas Panopoulos was asked to present his annual declaration of interest (DoI) and to further update the DoI to be in line with the EFSA guidance on declarations of interests. The DoI will be published on the EFSA website at: http://www.efsa.europa.eu/en/science/gmo/gmo_members.html.

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. There were no new applications on the agenda of this meeting.

4. ADOPTION OF THE MINUTES OF THE 28TH PLENARY MEETING HELD ON 13-14 SEPTEMBER 2006

The minutes of the 28th plenary meeting (13-14 September 2006) were adopted as proposed and will be published at:

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[3] Only present on 7 November 2006.

http://www.efsa.europa.eu/en/science/gmo/gmo_meetings/gmo_28th_plenmeet.html.

5. DISCUSSION AND POSSIBLE ADOPTION OF OPINIONS ON:

5.1. Safeguard clause invoked by Greece according to Article 23 of Directive 2001/18/EC

Introduction

EFSA received from the European Commission a request, under Article 29(1) and in accordance with Articles 22(2) and 22(5)(c) of Regulation (EC) No 178/2002, for a scientific opinion as to whether the scientific report and the scientific publications submitted by the Greek authorities show that there is an imminent danger for human health and the environment due to the cultivation of the maize varieties with the genetic modification MON810. EFSA should confine itself to the above terms of reference and does not need to consider elements, such as the fact that the decision of MON810 was given in 1998 and should be renewed, discussions in the Council, reference to the Cartagena Protocol, reference to the Greek Constitution, to the co-existence issues referred to in the introductory note. EFSA should analyse the scientific report documenting the hazard together with the bibliography.

The Panel invited the Greek scientific experts who have written the scientific report underlying the request for this safeguard clause, to discuss with them their scientific concerns and to identify whether there is new scientific evidence which was not considered in earlier risk assessments of the maize MON810.

Discussion

The Panel has investigated in depth the claims and documents provided by Greece. In these documents, the Panel did not identify any new data subject to scientific scrutiny or scientific information that would change the risk assessment conducted on MON810 maize which currently has marketing consent in the EU. In addition, the Greek submission did not supply scientific evidence that the environment or ecology of Greece was different from other regions of the EU sufficient to merit separate risk assessments from those conducted for other regions in the EU. The Panel considered the available data for MON 810 maize on molecular characterisation, food and feed safety together with available data on environmental impact. The Panel also reviewed new literature on CRY1Ab-expressing maize. The Panel concluded that MON810 maize is unlikely to have adverse effects on human and animal health or on the environment in the context of its proposed uses. The Panel therefore re-affirms its previous conclusions on the safety of MON810 maize.

The Panel, having considered the scientific information submitted by Greece, is of the opinion that

- there are no new data that would invalidate the initial risk assessment conducted on MON810 maize established under Directive 90/220/EEC or Directive 2001/18/EC,
- there is no specific scientific evidence, in terms of risk to human health and the environment, that would justify a prohibition of cultivation of MON810 maize authorised under Directive 90/220/EEC or Directive 2001/18/EC in Greece.

In conclusion, the Panel finds that the scientific evidence currently available does not sustain the arguments provided by Greece and that there is no imminent danger for human health and the environment due to the cultivation of the maize varieties with the genetic modification MON810.

Adoption

The opinion was adopted unanimously by the Panel. The opinion can be found on the EFSA website at:

http://www.efsa.europa.eu/en/science/gmo/gmo_opinions/ej411_greek_safeguard.html

6. UPDATE ON APPLICATIONS RECEIVED UNDER DIRECTIVE 2001/18/EC, REGULATION (EC) 1829/2003 AND REGULATION (EC) 1831/2003

6.1. Past scientific opinions

- EFSA received a request from the European Commission (DG ENV) for clarifications on the opinions issued by EFSA on the notifications for the placing on the market, under Part C of Directive 2001/18/EC of 1507 maize (C/ES/01/01) and Bt11 maize (C/F/96/05.10) (see also the minutes of 28th Plenary meeting[4]). The Panel provided clarifications concerning the impact on non-target lepidopteran species and risk management measures. Supported by the assessment of several notifications submitted under Directive 2001/18/EC and applications submitted under Regulation (EC) 1829/2003 on insect-resistant maize expressing different CRY proteins, and in the light of current scientific knowledge, the Panel re-affirms its former conclusions with respect to the potential impact of the CRY proteins on non-target organisms and in particular that Bt11 and 1507 maize are unlikely to have adverse effects on human and animal health or the environment in the context of their intended uses. These clarifications will be published on the EFSA website as an annex to the opinions on the insect resistant GM maize Bt11[5] and 1507[6].

- EFSA received from the Commission (DG ENV) a letter concerning a report funded by the Austrian government in relation to the Austrian safeguard clause on GM maize MON810 and T25 for which the Panel has already adopted a scientific opinion on 8 July 2004[7] and reconfirmed its assessment in a second scientific opinion adopted on 29 March 2006[8]. The Commission asked for EFSA's assistance in the study of this report, in order to determine whether the information of Austria can be considered as new information.

  The report entitled "Review of latest scientific evidence including latest findings concerning Austrian safeguard measures for GM-Maize lines MON810 and T25" contains statements on approaches to the risk assessment of GM maize MON810 and T25, including risk assessment of potential direct and indirect adverse effects and long-term effects, on human health and the environment. These statements were submitted by Austria as scientific justification for their proposed prohibition measures.

4 http://www.efsa.europa.eu/en/science/gmo/gmo_meetings/gmo_28th_plenmeet.html
5 http://www.efsa.europa.eu/en/science/gmo/gmo_opinions/922.html
6 http://www.efsa.europa.eu/en/science/gmo/gmo_opinions/827.html
7 http://www.efsa.europa.eu/etc/medialib/efsa/science/gmo/gmo_opinions/507.Par.0003.File.dat/opinion_gmo_safeguard_clauses_austria_en1.pdf
8 http://www.efsa.europa.eu/etc/medialib/efsa/science/gmo/gmo_opinions/1439.Par.0002.File.dat/gmo-op-ej338-safeguard-clauses_en1.pdf

This report and related research reports were reviewed and discussed by the Panel. In addition, the Panel is also aware of other recent scientific data published after the previous opinions of the Panel and not cited in the Austrian report, which are for instance mentioned in the opinion on the Greek safeguard clause on MON810 maize[9] as well as the clarifications provided on the adopted scientific opinions on GM maize Bt11 (comprising Cry1Ab and pat) and 1507 (comprising Cry1F and pat) (see above). Some of these are also of relevance for GM maize MON810 (comprising Cry1Ab) and T25 (comprising pat). On this basis and having considered all information presented for its scientific merit, the Panel considers that there is no new scientific evidence that would invalidate the adopted scientific opinions on the Austrian safeguard clause on GM maize MON810 and T25.

6.2. Ongoing applications

- The Panel discussed the procedure of delegating the environmental risk assessment to the competent authority for applications for cultivation submitted within the framework of Regulation 1829/2003, and more specifically how the questions for additional information raised by a competent authority should be managed. When a competent authority has been selected, bilateral meetings are taking place between EFSA and the competent authority to clarify the procedure and to discuss the draft assessment performed by the competent authority which should be in line with the specifications as laid down in the guidance document from the Panel for the risk assessment of GM plants and derived food and feed. In case the competent authority identifies questions for additional information in order to finalize the environmental risk assessment, EFSA will send the questions to the applicant (according to Articles 6&18, 2 of Regulation 1829/2003).

- Hybrid Cotton 281-24-236x3006-210-23 (Application EFSA/GMO/NL/2005/16; summary: http://www.efsa.europa.eu/en/science/gmo/gm_ff_applications/more_info/1026.html).

  The applicant sent a reply to the request of the Panel for additional information. As this information was not considered sufficient, the clock remains stopped as the Panel cannot proceed with the risk assessment.

7. UPDATE ON SELF TASK ACTIVITIES AND GUIDANCE ON GMO RISK ASSESSMENT

7.1. Self-tasking activity on animal feeding trials

A tenth working group meeting was held on 20 October 2006 to finalise the draft document for public consultation. The draft document will first be submitted to the Panel for possible adoption at the next plenary meeting in December and consequently be put on the EFSA website for public consultation.

7.2. Self-tasking activity on the assessment of allergenicity of GM foods/feed

A fourth working group meeting of the self-tasking on allergenicity of GM foods/feed took place on 26 October 2006. The working group decided to include, in addition to IgE mediated reactions, also

[9] http://www.efsa.europa.eu/en/science/gmo/gmo_opinions/ej411_greek_safeguard.html

non-IgE mediated reaction in the scope of the document. It was also decided to organise some sub-working group meetings on specified topics, such as on animal models.

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

A fourth working group meeting was held on 2 October 2006 during which the format of the document was discussed. The document will be complementary to the existing GM plant guidance document. Two specific stakeholder consultations are foreseen during the course of the finalisation of the document.

7.4. Renewal of authorisations of existing (notified) products

A new version of the draft guidance was presented to the Panel, focussing only on the renewal of authorisation of existing products and excluding for the moment renewals of products authorised according to Articles 7 and 19 of Regulation (EC) 1829/2003 as these applications will need to be submitted at the earliest one year before the expiry of the authorisation, which will not take place before 2015.

The aim of the new version of the guidance document is to assist applicants in the preparation and presentation of applications for renewal of authorisation of existing products according to Articles 11 and 23 of Regulation (EC) 1829/2003 on genetically modified food and feed. It is applicable for authorisation-holders who have products referred to as existing products, notified according to Articles 8 and 20, which have been published in the Community Register established according to Article 28 of the same Regulation. An application for renewal of authorisation for an existing product can only be submitted for the 26 products listed in the Community Register of existing products (http://ec.europa.eu/food/dyna/gm_register/index_en.cfm) and these have to be submitted before 18 April 2007.

Given the urgent need for guidance for these products, this document will be published on the EFSA website for public consultation for a limited period of two weeks (http://www.efsa.europa.eu/en/science/gmo/gmo_consultations/gmo_guidance_existing_products.html), allowing to have a finalised version shortly afterwards.

8. FEEDBACK FROM EFSA AND THE SCIENTIFIC COMMITTEE

The Panel was informed about the outcome of the 20th and 21st Plenary meetings of the Scientific Committee held on 14-15 September and 6-7 November 2006. The minutes of these meetings will be published at:
http://www.efsa.europa.eu/en/science/sc_commitee/sc_meetings/sc_20th_plenmeet.html and
http://www.efsa.europa.eu/en/science/sc_commitee/sc_meetings/sc_21st_plenmeet.html.

9. DATE OF FUTURE MEETINGS

Meeting dates were agreed at an earlier plenary meeting.

10. ANY OTHER BUSINESS

EFSA has compiled the comments from some Panel members and ad hoc experts on the draft guidelines for the conduct of food safety assessment of foods derived from recombinant-DNA animals and of foods derived from recombinant-DNA plants modified for nutritional or health benefits of the Codex Alimentarius Task Force on Foods derived from Biotechnology. These comments were sent to the Commission who is member of the Codex. The Commission took into account the comments from EFSA before sending the European Community comments to the Codex Alimentarius.

The Panel was informed about a new Codex discussion paper "Food Safety Assessment of the Low Level Presence of Recombinant-DNA Plant Material in Food Resulting from Asynchronous Authorisations", that will be on the agenda of the 6th Session of the Codex Ad Hoc Intergovernmental Task Force on Foods Derived from Biotechnology. Although the Panel has sympathy with the pragmatic approach taken in this document with respect to GMOs authorised in a third country according to the Codex principles, the Panel did not agree with the fact that it was referred to as a safety assessment as this is clearly an issue of risk management. It would be useful if the Codex could set up a database with all the information available of safety-assessed and authorised GM plants, which a third country would be able to consult when traces of this GMO are present in that country where no authorisation for that GMO exists.

As a follow-up to a previous meeting held in October 2005 in which representatives of the EFSA's GMO and PPR Panels, PRAPeR Unit and of the European Commission participated to discuss the issue of application of herbicides on GM crops[10], the Panel as well as the Chair of the PPR Panel were of the opinion that a second meeting would be necessary. The aim of this meeting would be to define an EFSA scientific view on the possible environmental impact of specific herbicides used on herbicide-tolerant crops.

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[10] See under Any Other Business of the minutes of the 21st Plenary meeting: http://www.efsa.europa.eu/en/science/gmo/gmo_meetings/1126.html.