MINUTES OF THE 43RD PLENARY MEETING OF THE SCIENTIFIC PANEL ON GENETICALLY MODIFIED ORGANISMS HELD ON 2-3 JULY 2008 IN PARMA, ITALY (ADOPTED ON 10 SEPTEMBER 2008)

AGENDA

PARTICIPANTS

GMO Panel:

Hans Christer Andersson, Salvatore Arpaia, Detlef Bartsch, Josep Casacuberta, Howard Davies, Niels Bohse Hendriksen, Lieve Herman, Sirpa Kärenlampi, Jozsef Kiss, Gijs Kleter, Harry Kuiper (Chair), Nickolas Panopoulos, Joe Perry, Annette Pöting, Joachim Schiemann, Willem Seinen, Jeremy Sweet and Jean-Michel Wal.

EFSA:
GMO Unit: Per Bergman, Elisa Bianco, Anna Christodoulidou, Yann Devos, Zoltan Diveki, Antonio Fernandez Dumont, Ana Gomes, Karine Lheureux, Sylvie Mestdagh and Claudia Paoletti.

European Commission:
Sébastien Goux and Michael Walsh (DG SANCO), Bernadette Murray[1] (DG ENV).

Ad hoc expert:
Hilko van der Voet[2].

APOLOGIES

GMO Panel:
Ilona Kryspin-Sorensen, Patrick du Jardin and Ingolf Nes.

---

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 invited to declare possible interests on topics included on the agenda. No specific declarations of interest were declared.

4. ADOPTION OF THE MINUTES OF THE 42ND PLENARY MEETING HELD ON 21-22 MAY 2008

The minutes of the 42nd Plenary meeting (21-22 May 2008) were adopted as proposed and will be published at:

http://www.efsa.europa.eu/EFSA/efsa_locale-1178620753812_1178710139228.htm

5. DISCUSSION AND POSSIBLE ADOPTION OF OPINIONS ON:

---

[1] Only present on 2 July
[2] Only present for item 5.3

5.1. Ice Structuring Protein (ISP) as a novel food ingredient (EFSA-Q-2008-073; NDA-GMO co-opinion)

Introduction

In accordance with Article 29 (1) (a) of Regulation (EC) No 178/2002, EFSA was requested by the European Commission to deliver a scientific opinion on the safety of 'Ice Structuring Protein (ISP)' as food ingredient in the context of Regulation (EC) No 258/97.

Discussion

The GMO Panel concluded that the recombinant DNA does not contain any sequence which causes safety concern and no DNA was detectable in the final product, therefore it was concluded that the recombinant DNA does not raise any safety concern

Adoption

The section of the co-opinion with regard to the risk assessment of the genetic modification of the application was adopted unanimously by the Panel. Once the NDA Panel section is adopted, the co-opinion will be published on the EFSA website at:
http://www.efsa.europa.eu/en/science/gmo/gmo_opinions.html.

5.2. MON89788 Soybean (application EFSA-GMO-NL-2006-36 under Regulation (EC) No 1829/2003; EFSA-Q-2006-182)

Introduction

In accordance with Articles 6(6) and 18(6) of Regulation (EC) No 1829/2003, the Panel was requested to carry out a scientific assessment of MON89788 soybean for food and feed uses, import and processing (EFSA-GMO-NL-2006-36).

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 provided by the applicant in reply to questions raised from Members States (MS) and GMO Panel.

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, the MS comments table and outstanding issues were discussed by the GMO Panel.

The GMO Panel is of the opinion that the molecular characterisation provided for the transformation event MON89788 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.

The comparative analysis has shown that soybean MON89788 is compositionally and agronomically equivalent to conventional soybean, except for the introduced traits. 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 MON89788 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-2006-36 concerns food and feed uses, import and processing. There is therefore, no requirement for scientific assessment on possible environmental effects associated with the cultivation of soybean MON89788 in the EU. Considering the scope of the application, in which cultivation is not contemplated, the GMO Panel is of the opinion that the likelihood of the spread and establishment of soybean MON89788 is very low and that unintended environmental effects due to this soybean will not be different from those ones 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 MON89788.

In conclusion, the GMO Panel considers that information available for soybean MON89788 addresses the comments raised by the Member States and considers that it is unlikely that soybean MON89788 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 (Annex G of the overall opinion) can be found on the following EFSA website at:
http://www.efsa.europa.eu/EFSA/efsa_locale-1178620753812_1178720362010.htm

5.3. Statistical consideration in the safety evaluation of GMOs (for public consultation) (Self-tasking activity; EFSA-Q-2006-080)

Introduction

The self-tasking activity of the Panel on "Statistical consideration in the safety evaluation of GMOs" started its activities in November 2005. The working group had several meetings between November 2005 and April 2008 to come to a finalised draft report for public consultation in July 2008.

Discussion

The draft report was presented to the Panel by the chair of the working group, Hilko van der Voet. The draft report presents recommendations in a general form on criteria for experimental design definition and statistical analysis of data.

The purpose of this document is the identification of a strategy for better harmonization of approaches for data evaluation in GMO risk assessment and a more precise definition of experimental design requirements for field trials for potential compositional, agronomic and phenotypic effects. Furthermore this report proposes statistical methods and possible analytic

approaches regarding equivalence. Results from any appropriate statistical analysis always require further interpretation with respect to a possible impact on human/animal health.

Adoption

The draft report was adopted unanimously by the Panel. The draft report will be available on the EFSA website for public consultation on the following website:
http://www.efsa.europa.eu/EFSA/efsa_locale-1178620753812_1211902010687.htm

5.4. Greek Ministerial Decision concerning the extension of validity and amendment of the previous Ministerial Decision on the trading of MON810 seeds (EFSA-Q-2008-313)

Introduction

Under Article 29(1) and in accordance with Articles 22(2) and 22(5)(c) of Regulation (EC) No 178/2002, EFSA received from the European Commission a request for a scientific opinion as "*to whether there is any scientific reason to deem that the placing on the market of MON810 seeds is likely to cause any adverse effects on human health and the environment, justifying the Greek safeguard measure.*"

On 11 June the Panel met Greek experts in a technical meeting at EFSA to discuss the scientific concerns and to identify whether there is new scientific evidence which was not considered in earlier risk assessments of maize MON810.

Discussion

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

Having considered the scientific information submitted by Greece as well as a broad range of relevant scientific literature, the GMO Panel is of the opinion that

- there is no new data that would invalidate the previous risk assessments carried out on maize MON810 (EFSA, 2005a[3], b[4]; EFSA, 2006b[5], c[6]),

[3] http://www.efsa.europa.eu/EFSA/efsa_locale-1178620753812_1178620770743.htm

[4] http://www.efsa.europa.eu/EFSA/efsa_locale-1178620753812_1178620770150.htm

[5] http://www.efsa.europa.eu/EFSA/efsa_locale-1178620753812_1178620769622.htm

- there is no specific scientific evidence, in terms of risk to human health and the environment, that would justify a prohibition of the placing on the market of maize MON810 authorised under Directive 90/220/EEC (repealed by Directive 2001/18/EC) and the prohibition of cultivation of maize MON810 varieties according to Directive 2002/53/EC in Greece.

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

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/efsa_locale-1178620753812_1178720400344.htm

5.5. Safeguard clause invoked by Austria according to Article 23 of Directive 2001/18/EC in relation to maize MON810 and T25 (EFSA-Q-2008-314)

Pending EFSA's request to the European Commission to clarify some procedural issues related to the safeguard clause invoked by Austria, the adoption of this opinion has been deferred.

5.6. Safeguard clause invoked by Austria according to Article 23 of Directive 2001/18/EC in relation to oilseed rape GT73 (EFSA-Q-2008-315)

Pending EFSA's request to the European Commission to clarify some procedural issues related to the safeguard clause invoked by Austria, the adoption of this opinion has been deferred.

5.7. Safeguard clause invoked by Hungary according to Article 23 of Directive 2001/18/EC in relation to maize MON810 (EFSA-Q-2008-316)

Introduction

Under Article 29(1) and in accordance with Articles 22(2) and 22(5)(c) of Regulation (EC) No 178/2002, EFSA received from the European Commission a request, for a scientific opinion "*to assess whether the information submitted by Hungary 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 GMO, for the uses laid down in the corresponding consent, constitute a risk to the environment.*"

On 11 June the Panel met Hungarian experts in a technical meeting at EFSA to discuss the scientific concerns and to identify whether there is new scientific evidence which was not considered in earlier risk assessments of maize MON810.

Discussion

The GMO Panel has investigated the evidence and documents provided by Hungary. In these documents which were presented and clarified by Hungarian authorities at the bilateral meeting, the

[6] http://www.efsa.europa.eu/EFSA/efsa_locale-1178620753812_1178620768611.htm

GMO Panel did not identify any new data subject to scientific scrutiny or scientific information that would change the previous risk assessments conducted on maize MON810 which currently has marketing consent in the EU. In addition the Hungarian submission did not supply scientific evidence that the environment of Hungary was different from other regions of the EU sufficient to merit separate risk assessments from those conducted for other regions in the EU. The GMO Panel considered all the available data on the possible environmental impacts of maize MON810. The GMO Panel reaffirms its previous conclusions on the safety of maize MON810 and reiterates its previous recommendation that a full risk assessment should be based on reliable data on toxicity, environmental exposure and statistical analysis of the impact on populations of non-target species.

Having considered the scientific information submitted by Hungary as well as a broad range of relevant scientific literature, the GMO Panel is of the opinion that

- there is no new data that would invalidate the previous risk assessments carried out on maize MON810 (EFSA, 2005a[7],b[8], 2006b[9],c[10]);
- there is no specific scientific evidence, in terms of risk to human and animal health and the environment, that would justify a prohibition of the placing on the market of maize MON810 authorised under Directive 90/220/EEC (repealed by Directive 2001/18/EC) and the prohibition of cultivation of maize MON810 in Hungary.

In conclusion, the GMO Panel finds that the scientific evidence currently available does not sustain the arguments provided by Hungary and that maize MON810 in Hungary is unlikely to have an adverse effect on human and animal health and the environment in the context of the uses laid down in the corresponding consent.

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/efsa_locale-1178620753812_1178720400903.htm

5.8. Statement in response to the request of the European Commission on the need for a 90 day rodent feeding study with genetically modified rice LLRICE62 (EFSA-Q-2008-342)

Introduction

EFSA received a request from the European Commission to reconsider the need of a 90-day toxicity study in rodents with the view to provide additional assurance of the LLRICE62 safety for risk managers considering that “it would constitute the first authorisation for GM rice in the EU” and “rice and its derived products are staple foods and constitute an essential part of the human diet”.

Discussion and adoption

---

[7] http://www.efsa.europa.eu/EFSA/efsa_locale-1178620753812_1178620770743.htm

[8] http://www.efsa.europa.eu/EFSA/efsa_locale-1178620753812_1178620770150.htm

[9] http://www.efsa.europa.eu/EFSA/efsa_locale-1178620753812_1178620769622.htm

[10] http://www.efsa.europa.eu/EFSA/efsa_locale-1178620753812_1178620768611.htm

In its scientific opinion[11] on the application EFSA-GMO-UK-2004-04 for the marketing of LLRICE62 (adopted on 30 October 2007), the GMO Panel concluded that the molecular characterisation of the DNA insert and flanking regions of LLRICE62 does not raise safety concerns, and that compositional analysis of samples of LLRICE62 and of conventional rice from a representative range of environments and seasons, indicated that both rough LLRICE62, and its processed products are compositionally equivalent to those of conventional rice, except for the presence of PAT protein which does not raise any safety concern. Furthermore field trials did not reveal any unexpected changes in agronomic performance and phenotypic characteristics. Since LLRICE62 is considered to be equivalent to commercial rice and there are no indications for unintended effects, the Panel concludes that no further animal feeding studies with the whole LLRICE62 are needed.

The GMO Panel prepared its opinion taking into consideration the information provided in the application, the scientific comments of the Member States and the additional information provided by the applicant. Up to now, no additional scientific information has become available that necessitates reconsideration of the conclusion in the Panel opinion that LLRICE62 is as safe as the conventional rice.

The statement can be found on the EFSA website at:
http://www.efsa.europa.eu/EFSA/efsa_locale-1178620753812_1211902011178.htm

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

6.1. Update on the request for a consolidated opinion on use of antibiotic resistance marker genes (ARM) as marker genes in GM plants

A meeting with the European Commission took place on 17 June and in view of the multiple aspects of the mandate, a new deadline for the adoption of the opinion has been proposed (December 15, 2008). Furthermore, the Panel has also been informed about an invitation from EFSA to EMEA to participate in this mandate on the use of ARM genes as marker genes in GM plants.

7. FEEDBACK FROM THE COMMISSION

The Panel was informed about the ongoing discussion between the European Commission and the Member States (MS) for the preparation of the legal framework for the safety assessment of GM food and feed. A first meeting between the European Commission and representatives of the MS was held on 16 June; during this meeting the EFSA Draft Update Guidance Document for the risk assessment of genetically modified plants and derived food and feed has been presented (see item 5.3 of the minutes of the 42nd Plenary meeting[12]).

[11] http://www.efsa.europa.eu/EFSA/efsa_locale-1178620753812_1178665910099.htm

[12] http://www.efsa.europa.eu/EFSA/efsa_locale-1178620753812_1178710139228.htm

The Commission representatives provided the Panel with the status of applications (LLcotton25 and A2704-12 soybean) that have been presented to the Standing Committee on the Food Chain and Animal Health for possible authorisation.

8. DATES OF FUTURE MEETINGS

Meeting dates for 2009 were agreed at earlier Plenary meetings.

9. ANY OTHER BUSINESS

The Panel was informed about the status of the safeguard clause invoked by France for maize MON810. In addition to the original documentation provided by the French authorities, an additional report was provided upon EFSA's request. The Panel will consider thoroughly the information package submitted and a technical meeting with French experts will be organised.

The French Food Safety Agency (AFSSA) had previously sent a letter to EFSA on toxicity studies made in the context of GMO safety assessment (see item 12 of the minutes of the 42nd Plenary meeting[13]). The Panel was informed about EFSA's reply to AFSSA in order to organise a technical meeting between experts.

The Panel was notified about the development of an OECD draft document on environmental considerations of biotechnologies. The Panel expressed its interest in the development of this document.

[13] http://www.efsa.europa.eu/EFSA/efsa_locale-1178620753812_1178710139228.htm