European Food Safety Authority

MINUTES OF THE 9TH PLENARY MEETING OF THE SCIENTIFIC PANEL ON GENETICALLY MODIFIED ORGANISMS HELD ON 2 APRIL 2004 (ADOPTED ON 22 APRIL 2004)

AGENDA

PARTICIPANTS

GMO Panel:
Hans Christer Andersson, Detlef Bartsch, Hans-Joerg Buhk, Colin Hill, Marc De Loose, Michael Gasson, Niels Hendriksen, Sirpa Kärenlampi, Harry Kuiper (Chair), Marco Nuti, Fergal O'Gara (Vice-Chair), Pere Puigdomenech Rosell, George Sakellaris, Joachim Schiemann, Angela Sessitsch, Jeremy Sweet (Vice-Chair), Jan Dirk Van Elsas and Jean-Michel Wal

Ad Hoc experts for agenda item5.1 :
Tony Hardy (PPR Panel) and Richard Phipps (University of Reading)

EFSA:
Suzy Renckens (scientific co-ordinator GMO Panel), Ellen Van Haver (assistant scientific co-ordination GMO Panel)

European Commission:
Andreas Klepsch (DG SANCO), Michael Walsh[1] (DG SANCO D5 – Interface unit), Barbara Weber (DG ENV)

[1] Attending afternoon session only.

APOLOGIES

GMO Panel:
Howard Davies, Willem Seinen and Ilona Kryspin-Sorensen

Ad Hoc experts for agenda item5.1:
Gerhard Flachowsky (FEEDAP Panel) and Andreu Palou (NDA Panel)

---

1. WELCOME AND APOLOGIES FOR ABSENCE

The Chairman opened the meeting and welcomed all. Apologies for absence were received from Howard Davies, Willem Seinen, Ilona Kryspin-Sorensen, Gerhard Flachowsky and Andreu Palou.

2. ADOPTION OF THE AGENDA

The agenda was adopted as proposed.

3. DECLARATION OF INTERESTS

Declarations of interests with regard to the GM maize MON863, MON863xMON810 applications were noted during the 5th Plenary meeting.

No interests were declared for the other agenda items.

4. ADOPTION OF THE MINUTES OF THE 8TH PLENARY MEETING HELD ON 3-4 MARCH 2004

The minutes of the 8th plenary meeting (3-4 March 2004) were adopted, subject to a few changes proposed by the Panel. The minutes of this meeting are published at:
http://www.efsa.eu.int/science/gmo/gmo_meetings/173/minutes_gmo_08_en_final1.pdf

5. DISCUSSION AND POSSIBLE ADOPTION OF OPINIONS ON:

5.1. Question from Commission regarding guidance for GM food and feed applications under Regulation (EC) 1829/2003: Guidance document for the risk assessment of GM plants and derived food and feed

Introduction

In accordance with Articles 5(8) and 17(8) of the Regulation (EC) N° 1829/2003 on genetically modified food and feed, EFSA has to publish detailed guidance – before the date of application of the Regulation on genetically modified (GM) food and feed which is 18 April 2004 – to assist the applicant in the preparation and the presentation of the application for authorisation of GM food and/or feed. The first draft guidance document prepared by the GMO Panel provides detailed

guidance for genetically modified plants and food and/or feed containing, consisting of or produced from these plants.

For this agenda item, *ad hoc* experts of the working group on GM food/feed guidance were invited as well.

Discussion and adoption

The rapporteur reported on the progress made since the last meeting of the working group held on 19 March 2004. The draft guidance document was discussed and adopted by the Panel by consensus. The draft document will be published on the EFSA website for a 3-week period of public consultation. The Panel will consider the written comments received from the public and discuss them during a stakeholder consultation on 25 May 2004. This consultation will focus on the scientific aspects of GM risk assessment.

5.2. Self tasking activity on antibiotic resistance markers

Introduction

Recognising the importance and urgency of the question, the GMO Panel decided to task itself to deliver a scientific opinion on antibiotic resistance genes with the potential to be used as marker genes for genetically modified plants and which may or may not have adverse effects on human health and the environment taking into account the limited availability of alternatives. The Panel set up a WG for this specific purpose that had prepared the draft opinion.

Discussion

The draft opinion on the use of antibiotic resistance genes as marker genes in genetically modified plants was presented to the Panel members during the plenary meeting.

As a main conclusion the opinion states that:

The GMO Panel considers the frequency of horizontal gene transfer from GM plants to other organisms as very low for all ARMGs considered. This, in itself, is an important consideration with regard to any risk posed by the use of ARMGs. However, with respect to clinical importance the Panel has categorised ARMGs into three groups with different potentials for compromising human health and the environment. ARMGs in the first group include genes conferring resistance to kanamycin and hygromycin. In this group the *npt*II gene, which confers kanamycin resistance, has a 13-year history of safe use in food crops and resistance to this group of antibiotics is widespread in naturally occurring microbes in humans and the environment. The Panel is of the opinion that with regard to safety there is no rationale for inhibiting or restricting the use of genes in this category, either for field experimentation or for the purpose of placing on the market. The second group of ARMGs, which includes resistance to chloramphenicol, ampicillin, streptomycin and spectinomycin, should be restricted to field trial purposes and should not be present in GM plants to be placed on the market. Given their current importance in clinical usage, we recommend that ARMGs placed in the third group, which includes those conferring resistance to amikacin and tetracyclines, are not present in GM plants to be placed on the market or in plants used for experimental field trials.

Adoption

The opinion was adopted by the Panel by consensus. There were no minority opinions. The opinion can be found on the EFSA website at:

http://www.efsa.eu.int/science/gmo/gmo_opinions/384_en.html

5.3. Two questions from the Commission on GM maize MON 863, MON 863xMON 810 (applications under 258/97 and 2001/18)

Introduction

The GMO Panel was tasked to provide a risk assessment of genetically modified maize MON 863 and the maize hybrid MON 863 x MON 810. The risk assessment is based on two questions raised by the Commission related to applications for the placing of the maize on the market by Monsanto under the Novel Food Regulation (EC) No 258/97 and the Directive 2001/18/EC on the deliberate release of genetically modified organisms (GMOs) into the environment.

The GMO Panel set up 3 working groups (WG) to examine simultaneously both applications: one WG dealt with the molecular characterization of the GMO, one WG dealt with food and feed issues (comparative analysis, toxicology and allergenicity) and the third WG studied the environmental aspects related to the proposed uses of the GM maize.

In its evaluation the Panel focused in particular on the issues that were raised by Member States (MS) during their initial assessment of the applications introduced under 258/97 and 2001/18/EC. The assessment is based on the information provided in the 2 applications including additional information from the applicant in reply to questions from MS and from EFSA.

Although the Panel will provide 2 separate opinions, as requested by the Commission because both applications were introduced within a different legislative framework, it does not discriminate in its assessment between the 2 applications, except for the environmental release aspect. Therefore, the assessment part of the opinion and the related opinion will be identical.

Discussion

The draft opinions were presented to the Panel members during the plenary meeting followed by a discussion on outstanding issues

As a main conclusion the opinions state that:

- The Panel considered that sufficient data were provided to address all outstanding questions raised by the Member States and concluded that the placing on the market of MON 863 maize is unlikely to have an adverse effect on human and animal health or the environment in the context of its proposed use.
- The GMO Panel also assessed the hybrid maize MON 863 x MON 810 which is produced by a conventional cross between inbred lines of maize MON 863 and MON 810. The Panel concluded that it was acceptable to use data for the single insert lines MON 863 and MON 810 in support of the safety assessment of the MON 863 x MON 810 hybrid. However the Panel was divided over the need for confirmatory data for the risk assessment of the hybrid, in particular the need for an additional 90-day rat study with MON 863 x MON 810. Therefore the Panel could not reach agreement on the safety evaluation of the hybrid.

Adoption

The opinions were adopted by the Panel by consensus. There were no minority opinions. The opinions can be found on the EFSA website at:

http://www.efsa.eu.int/science/gmo/gmo_opinions/381_en.html
http://www.efsa.eu.int/science/gmo/gmo_opinions/383_en.html