MINUTES OF THE 33RD PLENARY MEETING OF THE SCIENTIFIC PANEL ON GENETICALLY MODIFIED ORGANISMS HELD ON 16 MAY 2007 IN LJUBLJANA, SLOVENIA (ADOPTED ON 4 JULY 2007)

AGENDA

PARTICIPANTS

GMO Panel:
Hans Christer Andersson, Detlef Bartsch, Josep Casacuberta, Marc De Loose, Niels Bohse Hendriksen, Lieve Herman, Jozsef Kiss, Ilona Kryspin-Sorensen, Nickolas Panopoulos, Joe Perry, Joachim Schiemann, Willem Seinen, Jeremy Sweet (Chair).

EFSA:
GMO Unit: Zoltan Diveki, Karine Lheureux, Sylvie Mestdagh, Claudia Paoletti, Suzy Renckens, Ellen Van Haver.

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

APOLOGIES

GMO Panel:
Salvatore Arpaia, Howard Davies, Sirpa Kärenlampi, Harry Kuiper, Ingolf Nes, Annette Pöting and Jean-Michel Wal.

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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. Declarations of interests with regard to applications already announced during previous Plenary meetings are noted in the corresponding minutes.

As regards the new application (see item 8.2), one member[1] indicated that they in the future may be to some extent involved in the safety assessment process of this application at national level and provided a written declaration. It was decided from these declarations that there was no conflict of interest and that involvement in the national safety assessment process did not compromise the assessment of applications by EFSA.

[1] Detlef Bartsch

4. ADOPTION OF THE MINUTES OF THE 32ND PLENARY MEETING HELD ON 22-23 MARCH 2007

The minutes of the 32nd plenary meeting (22-23 March 2007) were adopted as proposed and will be published at:

http://www.efsa.europa.eu/en/science/gmo/gmo_meetings/gmo_32nd_meeting.html.

5. DISCUSSION AND POSSIBLE ADOPTION OF OPINIONS ON:

5.1. Guidance document for the risk assessment of GM plants containing stacked transformation events

Introduction

This guidance has the objective to outline the requirements for the risk assessment, under Regulation (EC) 1829/2003 and Directive 2001/18/EC, of GM plants containing stacked transformation events when the single events have already been assessed by the GMO Panel. The document will be used by the Panel when reviewing and updating its current guidance document for risk assessment of GM plants and derived food and feed[2].

Discussion

The draft document has been published on the EFSA website (from 6 July to 10 September 2006) for public consultation. The members of the working groups of the GMO Panel on molecular characterisation, food/feed safety and environmental risk assessment have carefully considered all comments received during this consultation and revised the document accordingly.

The Panel is aware that whilst current applications involve the stacking of two or three individual events, there is likely to be a move towards further increases in the numbers of events in GM stacks. As long as each event in the highest number of stacked events has been risk assessed, the risk assessment of the stacked events might also be applicable to GM stacks containing fewer of these events. Thus a single risk assessment of such a stack could cover all combinations with fewer of these events. However, applicants need to take into account the potential impact of any reduction in the number of events involved and should provide scientific argumentation for the absence of specific data on the stacked events with a lower combination of events.

EFSA is consulting the Commission on the practical implications of this approach.

Adoption

The guidance document was adopted unanimously by the Panel. It will be published on the EFSA website at:

http://www.efsa.europa.eu/en/science/gmo/gmo_guidance/gmo_guidance_ej512.html.

[2] http://www.efsa.europa.eu/en/science/gmo/gmo_guidance/660.html

6. UPDATE ON APPLICATIONS RECEIVED UNDER DIRECTIVE 2001/18/EC, REGULATION (EC) NO 1829/2003 AND REGULATION (EC) NO 1831/2003

Ongoing applications

- LLRice62 rice (application UK/2004/04): the applicant sent a reply to the request for additional information with respect to the molecular characterization, food/feed safety and environmental risk assessment. This additional information will be considered by the Panel at its next working group meetings on molecular characterisation, food/feed safety and environmental risk assessment.

- MIR604 maize (application UK-2005-11): following a request from the Panel for additional information, the applicant provided further compositional data which were assessed by the working group in charge of food/feed safety assessment and the additional data was considered satisfactory to proceed with the risk assessment.

- A2704-12 soybean (application NL-2005-18): the Panel requested further information from the applicant as regards the food/feed safety part of the application. The clock therefore was stopped as the Panel cannot proceed with the risk assessment.

- GA21 maize (application UK-2005-19): the applicant provided additional information on the molecular characterization of GA21 maize following a request from the Panel. The additional information will be considered in the next molecular characterization working group.

Renewals

The Commission representative informed the Panel that the Commission has received 20 applications for renewal of authorization for an existing (notified) product according to Articles 11 and 23 of Regulation (EC) No 1829/2003. These applications will be forwarded to EFSA once they have been checked to fulfill the requirements of the Regulation.

7. UPDATE ON MON 863 PUBLICATION

Following the request from the European Commission to examine the recently published CRIIGEN study on the statistical analysis of the GM maize MON 863 toxicology data and the Member States' consultation via the EFSA Advisory Forum (see item 10 of the minutes of the 32nd plenary meeting[3]), EFSA has received responses from nine Member States. These responses and the outcome of the ongoing evaluation by EFSA staff and *Ad Hoc* experts of the statistical methodology used in the CRIIGEN publication will be considered in the EFSA's response to the Commission.

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

8.1. Guidance on environmental and human health risk assessment of GM animals

[3] http://www.efsa.europa.eu/en/science/gmo/gmo_meetings/gmo_32nd_meeting.html

EFSA has received a request from the European Commission in the context of Article 29 of Regulation (EC) No 178/2002 to develop, building on the work done in the context of Codex Alimentarius, a guideline on the safety evaluation of GM animals that would address both food/feed safety and environmental safety of this technology. A specific annex on GM fishes is also requested, as these would be the first GM animals to be expected on the EU market (for ornamental and not for food/feed purposes). The Commission would like this guidance to be delivered by the end of 2007.

EFSA and the GMO Panel are monitoring the ongoing work within the Codex Alimentarius Task Force on foods derived from biotechnology, and more specifically the draft guideline for the conduct of food safety assessment of foods derived from recombinant-DNA animals and the report of the FAO/WHO Expert Consultation on the safety assessment of foods derived from GM animals, including fish[4]. The Panel considers it adequate to await the outcome of this activity at international level.

The Panel suggested that in first instance information needs to be gathered on GM animals' applications in the pipeline in the EU in order to decide on priorities with respect to the choice of the animals for which an in depth study might be most needed. Special attention is to be paid to the environmental aspects of the release of GM animals as these aspects are not covered by the Codex Alimentarius and the FAO/WHO Expert Consultation.

Given the high workload of the Panel, EFSA will consider to outsource (part of) this work within the framework of Article 36 of Regulation (EC) No 178/2002 enhancing cooperation and networking in Europe. The timeframe as proposed by the Commission is however too short and EFSA will propose a new timeframe.

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

EFSA received, via France, one new application (FR-2007-44 dried killed bacterial biomass PT73 Escherichia coli (THR)) within the framework of Regulation (EC) No 1829/2003 for an overall opinion including the scientific opinion on the GMO for import and processing, food and feed use.

Nominated risk assessment bodies of the Member States and national competent authorities 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. These comments will be considered during the scientific risk assessment of the application by the EFSA GMO Panel.

The summary of this application, as well as the information on their current status can be found on the following website:
http://www.efsa.eu.int/science/gmo/gm_ff_applications/catindex_en.html.

9. OUTCOME OF JOINT SESSION WITH EUROPEAN ADVISORY COMMITTEES ON BIOSAFETY HELD ON 15 MAY

[4] ftp://ftp.fao.org/docrep/fao/006/y5316E/y5316E00.pdf

A joint session of the GMO Panel and members of national Advisory Committees on Biosafety took place on 15 May pm, back to back to the 2nd meeting of the European Biosafety Advisory Committees in the field of the deliberate release of GMOs.

Panel members of the Environmental risk assessment working group briefly presented issues to be considered for the environmental risk assessment of GMOs and EFSA staff presented the procedure of delegating the environmental risk assessment to national competent authorities in the field of Directive 2001/18/EC for applications that concern GMOs to be used as seeds or other plant-propagating material. The presentations were followed by a discussion, and main discussion points included the issue of regional specificities within the environmental risk assessment, principles of evaluating non-target effects of GM plants, the risk assessment of GM plants containing stacked transformation events, the feasibility of general surveillance and how to assess long term effects. The members of the national Advisory Committees on Biosafety were also informed about and invited to the EFSA Scientific Colloquium on the environmental risk assessment of GM plants that will take place on 20-21 June in Tabiano, Italy[5].

10. UPDATE ON SELF TASKING ACTIVITIES AND GUIDANCE ON GMO RISK ASSESSMENT

10.1. Allergenicity assessment of GM foods

A sub-working group meeting was held on 14 March 2007 to discuss clinical aspects of the allergenicity assessment of GM foods/feed. IgE and non-IgE mediated reactions as well as coeliac disease have been addressed and will be further discussed at the next working group meeting. Telephone-conference meetings have also been held to discuss bioinformatics and *in vitro* tests for novel/transgenic proteins and *in vitro* analysis for the potential allergenicity testing of the whole GM plant.

10.2. Animal feeding trials

A 11th working group meeting was held on 16 March 2007 to discuss the comments on the draft document on the role of animal feeding trials within the safety and nutritional assessment of GM plants derived foods/feed received via the public consultation (from 15 December 2006 until 15 February 2007). The working group has considered the comments in its revision of the document. The aim is to present the revised version of the document to the Member State experts during a consultation meeting before finalising the document.

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

A 5th working group meeting was held on 1-2 March 2007 during which further risk assessment criteria were discussed for specific case studies of GM plants used for non-food/feed purposes.

10.4. Statistical considerations in the safety evaluation of GMOs

A fourth working group meeting took place on 19 March 2007. The working group will establish more specific guidance on how data should be presented and will provide recommendations for the experimental study design.

[5] http://www.efsa.europa.eu/en/science/colloquium_series/Colloquium_8_gmo.html

10.5. Working Groups of the Codex ad hoc Intergovernmental Task Force on Foods derived from Biotechnology

EFSA has provided scientific support to the European Commission in the Codex Working Group on Adventitious presence of rDNA material (Washington, 13-15 March) and the Codex Working Group on Foods derived from rDNA plants modified for nutritional or health benefits (Ottawa, 7-9 May).

11. FEEDBACK FROM EFSA AND THE SCIENTIFIC COMMITTEE

The 24th Plenary meeting of the Scientific Committee was held on 16-17 April 2007. The minutes of this meeting will be published at:
http://www.efsa.europa.eu/en/science/sc_commitee/sc_meetings/24th_sc_meeting.html.

12. DATES OF FUTURE MEETINGS

The November plenary meeting will be held on 22-23 November in Brussels, back to back to the Scientific Forum of EFSA's 5th Anniversary (20-21 November 2007). Consequently, the October and December Plenary meetings will need to be rescheduled.

13. ANY OTHER BUSINESS

The Panel discussed two proposals for outsourcing a task to a Member State institution within the framework of Article 36 of EFSA's founding Regulation (EC) 178/2002. The purpose of these assignments is to provide EFSA with a written scientific report on Cry proteins with a focus on their safety for human and animal health and the environment and with a report on the state-of-the-art on the impact of GM herbicide tolerant plants on non-target organisms. The final proposals will be published on the EFSA website.

EFSA has received a letter from the Dutch Competent Authority for Directive 2001/18/EC with comments on the EFSA guidance document for the risk assessment of GM microorganisms (GMMs) and their derived products intended for food and feed use[6]. The comments will be taken into account by the working group of the Panel on GMMs in the light of future revisions of the GMM guidance document.

The Panel was informed about the annual report, submitted to the Commission, on the implementation and the results of the monitoring activities for 1507 maize. This monitoring was carried out by Pioneer and Dow AgroSciences in accordance with Decision 2006/197/EC.

[6] http://www.efsa.europa.eu/en/science/gmo/gmo_guidance/gmo_guidance_ej374_gmm.html