MINUTES OF THE 24TH PLENARY MEETING OF THE SCIENTIFIC PANEL ON GENETICALLY MODIFIED ORGANISMS HELD ON 24-25 JANUARY 2006 (ADOPTED ON 28 MARCH 2006)

AGENDA

PARTICIPANTS

GMO Panel:
Hans Christer Andersson, Detlef Bartsch Hans-Joerg Buhk, Marc De Loose, Niels Bohse Hendriksen, John Heritage, Sirpa Kärenlampi, Harry Kuiper (Chair), Marco Nuti, Pere Puigdomenech, George Sakellaris, Joachim Schiemann, Willem Seinen, Jeremy Sweet (Vice-Chair), Jan Dick Van Elsas and Jean-Michel Wal.

EFSA:
Anna Christodoulidou (scientific officer), Karine Lheureux (scientific officer), Luisa Mannu (scientific officer), Sylvie Mestdagh (scientific officer), Claudia Paoletti (scientific officer), Suzy Renckens (scientific co-ordinator GMO Panel), Reinhilde Schoonjans (scientific officer), Ellen Van Haver (assistant scientific co-ordinator GMO Panel).

European Commission:
Werner Bosmans (DG ENV B), Michael Walsh (DG SANCO), Sébastien Goux (DG SANCO)

APOLOGIES

GMO Panel:
Howard Davies, Mike Gasson, Ilona Kryspin-Sorensen, Fergal O'Gara (Vice-Chair), Angela Sessitsch.

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1. WELCOME AND APOLOGIES FOR ABSENCE

The Chairman 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 new applications (NL-2005-26 GM maize NK603 x MON810, CZ-2005-27 GM maize MON 88017, NL-2005-28 GM maize 1507 x 59122, UK-2006-29 GM maize 59122 x NK603, UK-2006-30 GM maize 59122 x 1507 x NK603, NL-2006-31 GM maize LY038, NL-2006-32 GM maize LY038 x MON810, CZ-2006-33 GM maize MON 88017 x MON 810, C/NL/04/02 GM

carnation Moonlite 123.2.38), some members[1] indicated that they had been or in the future may be to some extent involved in the safety assessment process of these applications at national level and provided a written declaration. It was decided from these declarations that there was no conflict of interest and that the involvement in the national safety assessment process did not compromise the assessment of applications by EFSA.

4. ADOPTION OF THE MINUTES OF THE 23RD PLENARY MEETING HELD ON 6-7 DECEMBER 2005

The minutes of the 23rd plenary meeting (6-7 December 2005) were adopted as proposed. The minutes of this meeting are published at:

http://www.efsa.eu.int/science/gmo/gmo_meetings/1237_en.html

5. FEEDBACK FROM EFSA AND THE SCIENTIFIC COMMITTEE

The Panel was informed about the outcome of the 16th Plenary meeting of the Scientific Committee held on 12-13 December 2005. The minutes of this meeting are published at:

http://www.efsa.eu.int/science/sc_commitee/sc_meetings/1242_en.html

The Panel discussed some issues of the EFSA evaluation report that has been published on the EFSA website for public consultation. Comments from the Panel related to the case study on GMOs as described in the Annex to the report, the GMO risk assessment and communication and the composition of the Panel will be sent to the EFSA Director for further consideration.

6. FEEDBACK FROM THE COMMISSION

EFSA received a request from the Commission for scientific advice on a proposed draft guideline from the Codex Ad hoc Intergovernmental Task Force for the conduct of food safety assessment of food derived from recombinant-DNA animals. EFSA provided the Commission with some preliminary comments on the draft guideline. For future activities of the Codex in this field, EFSA will look into further possibilities to assist the Commission. The Panel also stressed the importance of considering the environmental impact of GM animals in the risk assessment.

7. DISCUSSION AND POSSIBLE ADOPTION OF OPINIONS ON:

7.1. Post Market Environmental Monitoring of GM plants

Introduction

[1] Christer Andersson (only for GM maize NK603 x MON810, MON 88017, LY038, LY038 x MON810, MON 88017 x MON 810), Detlef Bartsch, Hans-Jörg Buhk and Joachim Schiemann.

In April 2004, the Panel received the mandate to set up a working group on Post Market Environmental Monitoring (PMEM) to (i) develop guidance for applicants and risk assessors for the scientific evaluation of PMEM plans; (ii) invite and consult external experts for case-studies on monitoring plans; iii) organise consultation workshops with stakeholders; (iv) complement the Guidance Document of the Scientific Panel on GMOs for the Risk Assessment of GM plants and Derived Food and Feed and (v) assist EFSA in building a mutual understanding with the Commission, Member States and applicants on the assessment of specific PMEM plans.

Discussion

The draft opinion on PMEM was presented to the Panel members during the Plenary meeting. The opinion is summarised as follows:

A plan for Post Market Environmental Monitoring (PMEM) of genetically modified (GM) plants is mandatory in all applications for deliberate release submitted under EU Directive 2001/18/EC and EU Regulation 1829/2003. PMEM aims at identifying possible unanticipated adverse effects on human health or the environment which could arise directly or indirectly from GM plants. PMEM is composed of case-specific monitoring and general surveillance of GM plants. Case-specific monitoring is not obligatory but may be required to verify the environmental risk assessment, whereas a general surveillance plan must be part of the application. EFSA is responsible for assessing the scientific quality of PMEM plans submitted with each application. In this opinion, the Panel presents more specific guidance for applicants for developing PMEM plans. The Panel concludes that general surveillance can not be hypothesis driven, but should, when possible, make use of existing monitoring systems in addition to more focused monitoring systems (*e.g.* farm questionnaires). Data quality, management and statistical analysis are of high importance in the design of general surveillance plans and comparison should be made with baseline data. In addition the Panel explains the scientific rationale for this guidance and makes a number of recommendations for the management and conduct of PMEM by both applicants and risk managers.

Adoption

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

http://www.efsa.eu.int/science/gmo/gmo_opinions/1381_en.html

7.2. Safeguard clauses invoked under article 16 of Directive 90/220/EEC

The draft opinion on the safeguard clauses was presented to the Panel. Although the GMO Panel agreed on the scientific content of the draft opinion, the text needed some more work to put the text in the right format for publication. The final adoption of the opinion was referred to the next plenary meeting.

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

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

EFSA received, via the Netherlands, the Czech Republic and the UK, 8 new applications (NL-2005-26 GM maize NK603 x MON810, CZ-2005-27 GM maize MON 88017, NL-2005-28 GM maize 1507 x 59122, UK-2006-29 GM maize 59122 x NK603, UK-2006-30 GM maize 59122 x

1507 x NK603, NL-2006-31 GM maize LY038, NL-2006-32 GM maize LY038 x MON810 and CZ-2006-33 GM maize MON 88017 x MON 810) within the framework of Regulation (EC) No 1829/2003 for an overall opinion including the scientific opinion on the different GMOs for cultivation and/or 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 applications are valid. These comments will be considered during the scientific risk assessment of the applications by the EFSA GMO Panel.

In accordance with Article 6.3(c) and 19.3(c) of Regulation (EC) No 1829/2003, if an application concerns GMOs to be used as seeds or other plant-propagating material, EFSA shall ask a national competent authority within the meaning of Article 4 of Directive 2001/18/EC to carry out the environmental risk assessment. Therefore, EFSA will approach the national competent authorities under Directive 2001/18/EC for expression of interest to carry out the environmental risk assessment of applications EFSA-GMO-NL-2005-26, EFSA-GMO-NL-2005-28 and EFSA-GMO-UK-2006-29 and EFSA-GMO-UK-2006-30.

The summaries of these applications, 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.

8.2. Applications under Directive 2001/18/EC

EFSA received from the Commission a request for a scientific opinion on GM carnation Moonlite 123.2.38 from Florigene Limited introduced under Directive 2001/18/EC for import of the GM line (C/NL/04/02).

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

- MON 531 x MON 1445 cotton (application EFSA-GMO-UK-2005-09 under Regulation (EC) No 1829/2003); summary:
  http://www.efsa.eu.int/science/gmo/gm_ff_applications/more_info/775_en.html).

  The Panel has requested additional information on the molecular characterisation and food/feed safety of MON 531 x MON 1445 cotton. Clarification regarding the scope was also asked. More particularly, it is to be clarified (i) whether processing is included and (ii) does the application concern only refined oil or also crude oil to be used as feed. In the case of crude oil, particular attention should be given in the risk assessment with regard to the presence of DNA and protein in the crude oil. The clock for this application has been stopped.

- Phyzyme XP 5000L/G for pigs and poultry (EFSA-Q-2005-080) and Natuphos, 3-phytase for pigs and poultry (EFSA-Q-2005-116) within the framework of Regulation (EC) No 1831/2003.

  The risk assessment of the genetic modification of the GM microorganisms used in both applications is on the agenda of a working group meeting following the plenary meeting.

10. UPDATE ON SELF TASK ACTIVITIES AND GUIDANCE FOR GMO RISK ASSESSMENT

10.1. Self tasking activity on animal feeding trials

A follow-up of the sixth working group meeting on the use of animal feeding trials for whole GM food/feed, held on 23 January 2006, was presented to the Panel. A sub-working group will further elaborate on the final chapters of the draft document, addressing the potentialities and limitations of animal feeding trials with whole foods and the rationale for performing such studies.

10.2. Self tasking activity on post market environmental monitoring

The working group finalised the draft opinion addressing more general recommendations on post market environmental monitoring (PMEM) (see item 7.1).

10.3 Self tasking activity on the assessment of allergenicity of GM foods

The first meeting of the self task allergenicity of GM foods took place 13 December 2005. Work has been attributed to different subgroups to indicate the state-of-the-art and availability of methods for the different topics discussed (clinical aspects, structural aspects, in vitro studies, cell based tests, analytical and profiling technology and animal models).

11. FEEDBACK FROM THE MEMBER STATES

The Dutch Commission on Genetic Modification (COGEM) gave advice to the Dutch Authorities that the former objections of The Netherlands on the effects on non-target organisms and the persistence in the soil of the Cry1Ab protein are sufficiently answered in the EFSA opinion concerning Bt 11 cultivation (http://www.efsa.eu.int/science/gmo/gmo_opinions/922_en.html). In a letter from COGEM addressed to EFSA, a comment was made with respect to reference to the scientific literature in the EFSA opinion, in particular concerning dose response studies of pollen and accumulation of Bt proteins in the soil and in the food chain (see minutes of the 21st Plenary meeting of the GMO Panel).

The Panel shares the view with the COGEM experts that dose-response studies of pollen are important to assess the degree of effect of the toxin. Within the Bt 11 opinion, EFSA assessed in particular Dively et al. (2004)[2] representing the latest published study concerning the effects of Cry1Ab pollen on monarch butterflies. Cry proteins have different effects, and there is a range of susceptibilities within lepidopera to Cry1Ab, which was acknowledged in the EFSA Bt11 opinion by citing the review of Schmitz et al. (2003). Meanwhile, a new study has been published which suggests that deleterious effects on non-target butterflies are unlikely because of low pollen exposure doses (Shirai & Takahashi, 2005[3]).

Some Bt proteins are transferred from the Bt maize plant to different trophic levels in the environment. The Panel is of the opinion that there is no evidence of *accumulation* (in the sense of

[2] Dively, G.P., Rose, R., Sears, M.K., Hellmich, R.L. Stanley-Horn, D.E., Calvin, D.D., Russo, J.M. and Anderson, P.L., 2004. Effects on monarch butterfly larvae (Lepidoptera: *Danaidae*) after continuous exposure to Cry1Ab-expressing corn during anthesis. Environ. Entomol. 33(4), 1116-1125.

[3] Shirai, Y. and Takahashi, M., (2005) Effects of transgenic Bt corn pollen on a non-target lycaenid butterfly, *Pseudozizeeria maha*. Appl. Entomol. Zool. 40(1), 151-159.

continuous *concentration increase*, for example of a given protein in an environmental compartment) of Bt proteins in the food chain. Starting from an initial protein concentration in the maize plant, there is no report available that the protein *concentration* increases during carry-over to different compartments or trophic levels.

12. STAKEHOLDER ISSUES

EFSA provided assistance to the Commission in relation to questions received from a member of the European Parliament.

13. DATE OF FUTURE MEETINGS

The following new dates for plenary meetings in 2006 have been scheduled: 4-5 July, 13-14 September, 7-8 November and 5-6 December.

14. ANY OTHER BUSINESS

There was no any other business to be discussed.