European Food Safety Authority

MINUTES OF THE 18TH PLENARY MEETING OF THE SCIENTIFIC PANEL ON GENETICALLY MODIFIED ORGANISMS HELD ON 20-21 APRIL 2005 (ADOPTED ON 8 JUNE 2005)

AGENDA

PARTICIPANTS

GMO Panel:
Hans Christer Andersson, Howard Davies[1], Marc De Loose, Mike Gasson[1], Niels Bohse Hendriksen, John Heritage[2], Sirpa Kärenlampi, Ilona Kryspin-Sorensen, Harry Kuiper (Chair), Marco Nuti[1], Pere Puigdomenech, George Sakellaris, Joachim Schiemann, Angela Sessitsch[1], Jeremy Sweet (Vice-Chair) and Jan Dick Van Elsas.

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

European Commission:
Michael Walsh (DG SANCO D5 – Interface Unit), Sebastien Goux (DG SANCO D4)[1].

APOLOGIES

GMO Panel:
Detlef Bartsch, Hans-Joerg Buhk, Willem Seinen and Jean-Michel Wal.

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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.

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[1] Not present on 21 April.
[2] Present on 20 April in the afternoon.

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 a new application (LLCotton25[3]), some members indicated that they had been 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 the involvement in the national safety assessment process did not compromise the assessment of applications by EFSA.

4. ADOPTION OF THE MINUTES OF THE 17TH PLENARY MEETING HELD ON 2-4 MARCH 2005

The minutes of the 17th plenary meeting (2-4 March 2005) were adopted as proposed. The minutes of this meeting are published at:

http://www.efsa.eu.int/science/gmo/gmo_meetings/820/gmo_minutes_17th_plenmeet1.pdf

5. FEEDBACK FROM THE SCIENTIFIC COMMITTEE

The Chair gave an overview of the outcome of the 12th Plenary meeting of the EFSA Scientific Committee held on 14-15 April 2005. The Panel was informed about the public consultation on the draft opinion of the EFSA Scientific Committee on a Harmonised Approach for Risk Assessment of Compounds which are both Genotoxic and Carcinogenic (http://www.efsa.eu.int/science/sc_commitee/sc_consultations/882_en.html).

The minutes of the Scientific Committee meeting held on 14-15 April 2005 are published at:

http://www.efsa.eu.int/science/sc_commitee/sc_meetings/886/scm_12th_plenmeet_minutes2.pdf

6. DISCUSSION AND POSSIBLE ADOPTION OF OPINION ON:

6.1. Question from the Commission regarding guidance for GM food and feed applications under Regulation (EC) 1829/2003: Guidance on GM food/feed containing GMM

A draft version of the guidance document on food/feed derived from GMM was presented to the Panel members during the plenary, followed by a discussion.

As some points of the guidance document need to be further clarified, an additional meeting of the working group has been scheduled and the adoption of the document was referred to a next plenary meeting. The Panel discussed whether biofertilisation and bioremediation products should fall

[3] LLCotton25: declarations were made by Detlef Bartsch, Hans-Joerg Buhk and Joachim Schiemann.

within the scope of the GMM guidance document. As regarding the post-market monitoring, the Panel asked the working group to address this issue as it is requested by the current legislation.

6.2. Question from Commission regarding GM maize Bt11 (notification C/FR/96/05.10 under 2001/18/EC)

Introduction

The GMO Panel was asked to provide a scientific opinion as to whether there is any scientific reason to believe that placing on the market of Bt11 maize for cultivation, feed and industrial processing is likely to cause any adverse effects on human health and the environment within the scope of Directive 2001/18/EC (notification C/FR/96/05.10).

Discussion

The GMO Panel set up 3 working groups (WG) to examine the Bt11 application: one WG dealt with the molecular characterisation of the GMO, one dealt with food and feed issues (comparative analysis, toxicology and allergenicity) and the third WG studied the environmental aspects (including post market environmental monitoring) related to the proposed uses of the GM maize.

The assessment is based on the information provided in the application, including additional information from the applicant in reply to questions from Member States (MS) and from EFSA.

The draft opinion was presented to the Panel members during the plenary meeting followed by a discussion on outstanding issues.

As a main conclusion the opinion states that:

Maize line Bt11 has been developed for protection against lepidopteran pests by expressing the Cry1Ab protein. The introduction of a *pat* gene confers tolerance to glufosinate ammonium. The GMO Panel has assessed information provided on the molecular characteristics of the insertion, the safety of the proteins expressed and the potential for risks associated with any changes to the nutritional, toxicological and allergenic properties of Bt11 maize. Analysis of the chemical composition of the maize and field trial data were also used to assess the potential for changes to safety, nutritional as well as agronomic parameters. No data have emerged to indicate that maize line Bt11 is any less safe than its non-GM comparators.

The Panel considers that Bt11 maize will have impacts similar to those of comparable non-GM maize cultivars on the environment. The only adverse effect identified was the possibility that resistance to Cry1Ab protein might evolve in corn borers exposed to Bt11 maize following cultivation for some years. The Panel accepts the monitoring plan developed by the applicant to monitor specifically for resistance in corn borers and recommends that cultivation should be accompanied by appropriate risk management strategies to minimise exposure of non-target insects and to delay the development of resistance to the Cry1Ab protein in target insects. In addition, the Panel accepts in principle the general surveillance plan submitted by the applicant.

From the data provided by the applicant, there was no evidence to indicate that Bt10 material was present in the Bt11 maize used for the biosafety studies. Therefore, the GMO Panel considers that the risk assessment of Bt11 maize has not been compromised by the presence of Bt10 maize.

The EFSA GMO Panel is therefore of the opinion that there is no evidence to indicate that placing of maize line Bt11 and derived products on the market is likely to cause adverse effects on human or animal health or the environment in the context of its proposed use.

The authorisation of the complementary herbicide is not within the remits of this opinion and is covered by other legal frameworks of the EU and Member States.

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/922/gmo_opinion_ej213_bt11maize_cultivation_en1.pdf

7. MON863 x MON810 MAIZE: 90-DAY TOXICITY STUDY

EFSA received the full data package on the 90-day rat study within the framework of 2 applications of the hybrid maize MON 863 x MON 810: application EFSA-GMO-DE-2004-03 under Regulation (EC) 1829/2003 and application C/DE/02/09 under Directive 2001/18/EC. On 2 April 2004, the Panel issued an opinion stating 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 and could therefore not reach agreement on the safety evaluation of the hybrid. To resolve this issue, EFSA requested in April 2004 the 90-day study in question from the applicant in order to allow the Panel to conclude its evaluation.

The evaluation of the 90-day rat study will be subject of the next working group meetings on applications of the GMO Panel.

8. PROGRESS REPORTS ON:

8.1. Assessment of hybrids

The extend of data for the risk assessment of hybrids was discussed by the Panel. For future applications on hybrids, the three working groups on applications will address the requirements needed for the molecular characterisation, the food/feed safety and the environmental risk assessment of hybrids.

8.2. Self tasking activity post market environmental monitoring

The next working group meeting on post market environmental monitoring has been scheduled for 31 May 2005. Chapter 11.4 (General surveillance of the impact of the GM plant) of the EFSA guidance document of the GMO Panel for the risk assessment of GM plants and derived food and feed will be finalised and a public consultation will be launched.

8.3. Self tasking activity on animal feeding trials

A follow-up of the second working group meeting on animal feeding trials held on 6 April 2005 was presented to the Panel. The members discussed the outline of issues to be addressed by the working group and some first contributions to these tasks from working group members.

8.4. Self tasking activity on allergenicity assessment of GM foods

Following the request from the GMO Panel for a self tasking activity on "the allergenicity assessment of GM foods", a letter from the EFSA Director of Science was sent to the Panel to support this activity. External experts recognised for their competence in specific scientific fields of allergenicity assessment will be contacted by the EFSA secretariat. The working group will have its first meeting in autumn 2005

9. NEW REQUESTS FROM COMMISSION: DISCUSSION AND ADOPTION OF MANDATES

9.1. Safeguard clause Hungary

EFSA received from the Commission a request for a scientific opinion on the statement and documents submitted by Hungary in the context of the safeguard clauses invoked under Article 23 of Directive 2001/18/EC. EFSA is requested to provide a scientific opinion as to whether the statements and documents submitted by the Hungarian authorities comprise new or additional information affecting the environmental risk assessment or re-assessment of existing information on the basis of new or additional scientific knowledge such that detailed grounds exist to consider that the authorized MON 810 maize (reference C/F/95/12-02), for the uses laid down in the corresponding consent, constitute a risk to human health or the environment.

9.2. Question from the Commission regarding GM maize NK603 x MON810 (application C/GB/02/M3/3 under Directive 2001/18/EC)

EFSA received from the Commission a request for a scientific opinion on GM maize hybrid NK603 x MON810 from Monsanto introduced under Directive 2001/18/EC (EFSA-Q-2005-056) for import and processing, including use in animal feed, (C/GB/02/M3/3).

10. UPDATE ON APPLICATIONS RECEIVED UNDER DIRECTIVE 2001/18/EC

10.1. LLRice62: Question from the Commission regarding application C/GB/03/M5/3 under Directive 2001/18/EC

This item was discussed together with application EFSA-GMO-UK-2004-04 under Regulation (EC) 1829/2003. The Panel is awaiting additional information from the applicant.

10.2. Question from Commission regarding GM oilseed rape MS8, RF3 and MS8 x RF3 (application C/BE/96/01 under 2001/18)

EFSA received from the Commission a request for a scientific opinion on GM oilseed rape MS8, RF3 and MS8xRF3 introduced under Directive 2001/18/EC (EFSA-Q-2005-003). EFSA is awaiting clarification from the applicant and the Commission regarding the scope of the application and the terms of reference received from the Commission. As stated in the request provided to the

Commission, the applicant is not longer interested in cultivation and the rapporteur Member State has suggested the possible exclusion of cultivation as a condition for consent of MS8, RF3 and MS8 x RF3. EFSA therefore intends only to provide a scientific opinion on import, processing for feed and industrial uses but not on the cultivation part of the application.

10.3. Question from Commission regarding GM potato EH92-527-1 (application C/SE/96/3501 under 2001/18)

Application GM potato EH92-527-1 introduced under Directive 2001/18/EC for cultivation and production of starch is under evaluation by the three working groups (molecular characterisation, food/feed safety and environmental risk assessment) of the GMO Panel.

11. UPDATE ON APPLICATIONS RECEIVED UNDER REGULATION 1829/2003

Since last Plenary meeting, EFSA received, via the Netherlands, one additional application within the framework of Regulation (EC) 1829/2003, bringing the total number of applications received by EFSA under this Regulation to thirteen.

New application (under completeness check):
EFSA-GMO-NL-2005-13: LLCotton25

The summary of the application can be found on the following website: http://www.efsa.eu.int/science/gmo/gm_ff_applications/catindex_en.html.

12. APPOINTMENT OF RAPPORTEURS FOR NEW QUESTIONS

Rapporteurs have been appointed for the new applications mentioned under items 9&11.

13. UPDATE ON BT10 MAIZE

The GMO Panel was informed about the statement on Bt10 maize issued by EFSA on 12 April 2005 (http://www.efsa.eu.int/press_room/press_statements/884/efsa_statement_bt10maize_en1.pdf) and about the decision taken by the Commission on emergency measures regarding Bt10 in maize products (http://europa.eu.int/eur-lex/lex/LexUriServ/site/en/oj/2005/l_101/l_10120050421en00140016.pdf%20).

After the issues resulting from the presence of Bt10 maize in some batches of Bt11, the GMO Panel would like to stress the need for applicants to confirm the authenticity of the material used for biosafety studies. Ideally, a declaration of authenticity should be attached to the samples deposited in the relevant depositories. Applicants are reminded that they should keep reference samples of the material used for the specific studies.

14. APPLICATIONS REGARDING FEED ADDITIVES PRODUCED BY GMMS

The current legislation on feed additives (Regulation (EC) 1831/2003) states that for GMO-derived additives the applicant should provide the authorization granted in accordance with the applicable legislation on GMO food and feed (Regulation (EC) 1829/2003). For this kind of applications, the GMO Panel and the FEEDAP Panel will draft and adopt a co-opinion. The GMO Panel will perform the risk assessment dealing with the genetic modification event and following the approach agreed in drafting the GMM guidance document (currently being finalised), while the FEEDAP Panel will assess the safety of the additive. The same procedure will be followed for GMO-additives under Directive 70/524/EEC concerning additives in feedingstuffs.

A Working Group of the GMO Panel will be created for the assessment of GMO-derived additives within the framework of Directive 70/524/EEC and Regulation (EC) 1831/2003.

15. FEEDBACK FROM THE EFSANET LAUNCH

On 16 March 2005, EFSA's GMO Unit organised a first review of the GMO EFSAnet after one year of activity with the Member States' members of the GMO EFSAnet. The GMO EFSAnet provides privileged access to Member States' competent authorities, the European Commission (EC) and the Community Reference Laboratories (JRC-CRL) to all information related to applications sent by an applicant to EFSA within the framework of Regulation (EC) 1829/2003. During the one-day meeting, users from the Member States expressed their satisfaction with the current system.

16. STAKEHOLDER ISSUES

The Panel was informed about the different requests for public access to applications or certain parts/documents of the applications.

In accordance with requirements of Regulation 1049/2001 on public access to European Parliament, Council and Commission documents, EFSA gives access, after consultation, to non-confidential parts of the application to the person who has requested public access (see the minutes of the 17th Plenary meeting of the GMO Panel on the procedure to be followed under Regulation (EC) 1049/2001).

EFSA has to take duly account of specific provisions as regards confidentiality set out in Community legislations governing the scientific evaluation of substances, products or procedures subject to a system of prior authorisation. According to Directive 2001/18/EC on the deliberate release into the environment of genetically modified organisms it is up to the rapporteur Member State to determine if information claimed to be confidential by an applicant is to be classified as such. According to Regulation (EC) 1829/2003 on genetically modified food and feed it is the task of the Commission to decide, after consultation with the applicant, which information should be kept confidential. Until then EFSA can not disclose the information claimed by the applicant as confidential business information.

17. DATES OF FUTURE MEETINGS

The Plenary meeting in October 2005 will take place in Brussels from 13-14 October (instead of 25-26 October).

18. ANY OTHER BUSINESS

Following the 17th Plenary meeting, the Panel had a further discussion on the mandate of a new self tasking activity on the production of plant made pharmaceuticals in genetically modified crops. The draft mandate will be distributed after the Plenary meeting to the Panel members for final comments.
