European Food Safety Authority

MINUTES OF THE 3RD PLENARY MEETING OF THE SCIENTIFIC PANEL ON GENETICALLY MODIFIED ORGANISMS HELD ON 2 OCTOBER 2003 (ADOPTED ON 7 NOVEMBER 2003 BY WRITTEN PROCEDURE)

AGENDA

PARTICIPANTS

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

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

European Commission:
Michael Walsh (DG SANCO D5 – Interface unit)

1. WELCOME AND APOLOGIES FOR ABSENCE

The Chairman opened the meeting and welcomed all. All Panel members were present. Apologies for absence were received from Andrew Tommey (DG Environment).

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.

In the case of the geneticaly modified (GM) maize NK603 dossiers, listed under agenda item 7.1, several members indicated that they were to some extent involved in the safety assessment process of these GMO applications at national level[1]. Each member was invited to complete a specific form for specifying their declaration, where applicable. 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 the two dossiers by EFSA but that for transparency reasons this would be mentioned in the minutes of the meeting.

While awaiting a general guideline for the declaration of interests, it was decided that when members are directly involved in the risk management process of GMO authorisations in their country, they can contribute to the scientific discussions but will not take part in the final adoption of the opinion.

4. MINUTES OF THE PREVIOUS MEETING

The minutes of the 2nd plenary meeting (4 July 2003) were adopted. The minutes of this meeting are published at: http://www.efsa.eu.int/pdf/minutes_gmo_02_adopted_en.pdf

5. FEEDBACK FROM THE SCIENTIFIC COMMITTEE

5.1. Advice of the Scientific Committee on guidelines for the preparation of requests for scientific opinions

A copy of the guidelines for the preparation of requests for scientific opinions (ref. EFSA/SC/11 Final) was distributed during the meeting. There was no particular discussion on this subject.

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[1] Declarations were noted from Hans Christer Andersson, Detlef Bartsch, Hans-Joerg Buhk, Andrew Chesson, Sirpa Kärenlampi, Gijs Kleter, Harry Kuiper and Joachim Schiemann. Most declarations were already made during the working group meetings dealing with NK603 on 17 September 2003.

5.2. Minutes of the 2nd plenary meeting of the EFSA Scientific Committee held on 27 and 28 August 2003

The Chair gave an overview of the outcome of the 2nd meeting of the Scientific Committee (SC) held on 27 – 28 August 2003. The minutes of this meeting are published at:
http://www.efsa.eu.int/pdf/minutes_sci_02_adopted_en.pdf.

5.3. EFSA proposal on format of scientific opinions

At its last meeting the Scientific Committee agreed on a revised version of the working document 'EFSA proposal on format of scientific opinions'. As major changes to the document it was decided to mention the names of the panel members at the end of an opinion and not at the start and to acknowledge *ad hoc* experts only.

The GMO panel is in favour of acknowledging all participants of a working group that prepare an opinion, Panel members as well as the *ad hoc* experts. The Chairman will report this to the Scientific Committee.

5.4. Feedback from the 3rd plenary meeting of the EFSA Scientific Committee held on 17 and 18 September 2003

During the last meeting of the Scientific Committee, different working groups have been established.

1. Working Group on Exposure assessment of contaminants, residues, pesticides and food items
2. Undesirable substances in feed
3. Working Group on Emerging Risks (EMRISK)
4. Working Group on a Uniform Approach for Genotoxic and Carcinogenic Substances (GENTOX)
5. Working Group on EFSA's Crisis Management Plan

The Chairman invited the members of the GMO panel to indicate possible interest for participation in either of these working groups. The names of interested Panel members will be communicated to the Scientific Committee.

6. NEW REQUESTS TO GMO PANEL: UPDATE DRAFT WORK PROGRAMME – DISCUSSION AND ADOPTION OF THE MANDATES

The scientific coordinator gave an overview of the different actual and potential upcoming requests to the GMO panel and provided the specific mandates for the new questions and related correspondence to the Panel. Most questions from the Commission relate to authorisation dossiers introduced under Directive 2001/18/EC and/or under Regulation (EC) 258/97. Although mandates to EFSA have to be presented formally during a plenary meeting of the Panel, some of the activities have already started before this plenary meeting in order to be able to meet the proposed deadlines.

The GMO Panel received following requests:

- EFSA-Q-2003-002: GM maize NK603 food safety – Dossier submitted under Regulation 258/97.

- EFSA-Q-2003-003: GM maize NK603 environmental safety – Dossier submitted under Directive 2001/18/EC (C/ES/00/01).
- EFSA-Q-2003-004: Guidance notes related to the contained use of genetically modified micro-organisms under Directive 90/219/EEC.
- EFSA-Q-2003-005: Guidance for applications under the new GM food and feed Regulation.
- EFSA-Q-2003-078: GM oilseed rape GT73 environmental safety – Dossier submitted under Directive 2001/18/EC (C/NL/98/11) – advance copy of the request.

An overview was also given of existing and new legislations and proposals for new legislations for which the GMO panel is to be or may be consulted:

- Directive 2001/18/EC of the European Parliament and of the Council of 12 March 2001 on the deliberate release into the environment of genetically modified organisms and repealing Council Directive 90/220/EEC
- Regulation (EC) No 258/97 of the European Parliament and of the Council of 27 January 1997 concerning novel foods and novel food ingredients.
- Regulation (EC) No 1829 /2003 of the European Parliament and of the Council of 22 September 2003 on genetically modified food and feed[2]
- Regulation (EC) No 1831 /2003 on additives for use in animal nutrition (17 March 2003)
- Draft proposal for a Regulation on food additives authorised for use in foodstuffs intended for human consumption
- Draft proposal for a Regulation on enzymes used or intended for use in food

A member also noticed that there is a proposal for a Directive on environmental liability with regard to the prevention and remedying of environmental damage that possibly could have implications for the work of the GMO panel.

7. PROGRESS REPORTS

7.1. Two questions from the Commission on GM maize NK603 (applications under Regulation (EC) 258/97 and Directive 2001/18/EC)

EFSA has received from the Commission 2 separate requests for a scientific opinion relating to applications for the placing on the market of GM maize NK603 introduced within the framework of Regulation (EC) 258/97 and Directive 2001/18/EC, respectively (questions EFSA-Q-2003-002 and EFSA-Q-2003-003, see above). NK603 maize is genetically modified to provide resistance to the herbicide glyphosate, also known as Roundup. The scope of the applications relates to import and food and feed use, not cultivation.

Since a substantial part of these notification contains exactly the same scientific information (e.g. on molecular characterization, toxicology and allergenicity studies, compositional analysis, etc.) EFSA expressed preference to have both questions addressed at the same time in line with the provisions of Art 6 of 1304/2003[3] concerning the combining of requests. However, because both applications were introduced within a different regulatory framework, the Commission insisted on receiving two separate opinions. It was agreed that a common risk assessment part of the opinions

[2] This Regulation was published on 18 October 2003

[3] Regulation (EC) No 1304/2003 of 23 July 2003 on the procedure applied by the European Food Safety Authority to requests for scientific opinions referred to it

could be based on the information provided in both applications, but that differences in legislation should be highlighted in the background. The opinions should pay specific attention to the scientific objections raised by the competent authorities of the Members States in the context of Directive 2001/18/EC and Regulation (EC) 258/97.

Because of the short timeframe within which EFSA is requested to deliver an opinion (before end of November 2003), it was decided to start the scientific evaluation of these notifications prior to this meeting. Three working groups were created to deal with these applications: a working group 'Molecular characterisation', a working group 'Food/feed safety' and a working group 'Environmental Risk Assessment'. At the first meeting of the working groups on 17 September 2003, representatives of the Commission introduced the questions to the experts.

Each working group prepared a report that was compiled by the overall rapporteur into a first draft of the opinion that was presented during the plenary meeting. Remaining questions were further discussed and agreement was reached on the format of the draft opinion.

7.2. Self tasking activity on antibiotic resistance markers

At the last plenary meeting it was decided to set up a working group to deliver a scientific opinion on the use of antibiotic resistance marker genes in GMOs, in line with the provisions of art 4 (2) Directive 2001/18/EC: '*Member States and the Commission shall ensure that GMOs which contain genes expressing resistance to antibiotics in use for medical or veterinary treatment are taken into particular consideration when carrying out an environmental risk assessment, with a view to identifying and phasing out antibiotic resistance markers in GMOs which may have adverse effects on human health and the environment. This phasing out shall take place by the 31 December 2004 in the case of GMOs placed on the market according to part C and by 31 December 2008 in the case of GMOs authorised under part B.'*

The Panel is aware that the Committee of the Competent Authorities of Directive 2001/18/EC set up a *Working Group on the implementation of Article 4 (2) of Directive 2001/18/EC*. An opinion from the GMO panel could give additional support to the work of this group.

The coordinator of the working group on 'antibiotic resistance marker genes' gave an overview of the activities of the working group so-far: the working group held meetings on 28 August and 1 October 2003. The working group drafted a document including background and terms of reference that was presented to the plenary meeting and adopted:

*The Panel tasks itself to draft a scientific opinion on 'Antibiotic resistance genes with the potential to be used as marker genes for genetically modified plants and which may have adverse effects on human health and the environment taking into account the limited availability of alternatives'***.**

The working group gathered recent reviews and publications on the topic. The Panel was informed of the outcome of the European Network on Safety Assessment of Genetically Modified Food Crops (ENTRANSFOOD). It was decided not to repeat the excellent reviewing work already done by others but to indicate where there is consensus among scientists and come to clear conclusions and recommendations while referring to the relevant literature. The opinion should mainly focus on antibiotic resistance marker genes currently used in GM plants and only briefly address alternative methods. At later stage a second opinion could deal with the risk assessment of alternative methods in more detail, if more information would become available on such methods.

One additional meeting of the working group on antibiotic resistance marker genes is foreseen.

7.3. Question from Commission regarding GMM guidelines for contained use

EFSA received a request (EFSA-Q-2003-004) to provide a scientific opinion on the draft Annex "Guidance notes supplementing Part B of Annex II to Directive 90/219/EEC on the contained use of genetically modified micro-organisms", which were reviewed by the Scientific Committee on Plants (SCP) in September 1999. In particular, EFSA is requested to verify if there is any new scientific knowledge or developments that may have arisen since SCP issued its opinion in 1999.

A working group was set up to deal with this specific request relating to the contained use of genetically modified micro-organisms. The coordinator of the working group reported on the meeting held on 1 October 2003.

8. DISCUSSION ON WORKING PROCEDURES AND SETTING UP OF WORKING GROUPS, INVOLVEMENT OF *AD HOC* EXPERTS

Following the experience with the NK603 evaluation, the Panel agreed that the assessment of the application by the 3 working groups was a good working procedure that would be continued for future dossiers. The coordinator of one of the working groups acted as overall rapporteur for the opinion. It was agreed that the formula whereby the experts receive from EFSA password-protected CD-ROMs, prepared by the applicant, is the most appropriate way to transmit the information fast, provided the files are well labelled and ordered and a very detailed table of contents is provided to allow rapid search of the necessary information.

The setting up of working groups and the involvement of *ad hoc* experts were discussed under agenda items 9 and 10.

9. APPOINTMENT OF RAPPORTEURS FOR NEW QUESTIONS

EFSA has received advance notice of a new question - that will be transmitted to EFSA for evaluation soon - regarding application for placing on the market GM oilseed rape GT 73 (EFSA-Q-2003-078) under Directive 2001/18/EC. Requests for opinions regarding 2 applications for the marketing of GM hybrid maize MON863xMON810 under Directive 2001/18/EC and Regulation 258/97 may come shortly. For each of these dossiers rapporteurs were appointed to coordinate the working groups to assess respectively the molecular data, comparative and food/feed analysis, and the environmental aspects of these applications.

The GMO panel received a request to establish guidance notes for applications introduced within the framework of the new GM food and feed Regulation (question EFSA-Q-2003-005). This guidance document should be established before the date of application of the new GM food and feed Regulation by mid April. EFSA informed the GMO panel that the Commission informally agreed that, because of the short timeframe of 6 months, the scope of the guidance document could be limited to food and feed derived from GM crops. Next priority will be given to guidance for food and feed derived from GM micro-organisms. At later stage, also guidance notes on other kind of GMOs (e.g. GM food/feed with altered composition, food/feed derived from GM animals) should be established.

The EC Guidance document for the risk assessment of genetically modified plants and derived food and feed, prepared by the Joint Working Group on Novel Foods and GMOs

(http://europa.eu.int/comm/food/fs/sc/ssc/out327_en.pdf) will be used as the basis for further discussion. As was the case for that document, the Panel decided that also the aspects relating to the environmental risk assessment (including the post market monitoring) should be covered in the EFSA guidance document. The representative of the Commission agreed with the proposed approach. A working group was established and it was decided to invite *ad hoc* experts from the Panel on feed additives, the Panel on dietetic products, nutrition and allergies and the Panel on plant health, plant protection products and their residues.

10. DISCUSSION ON SELF TASKING

In addition to the formal legal questions to the GMO panel, projects of self tasking identified at the last plenary meeting were also discussed. It was however clarified that before a self tasking project can be accepted, the background and the terms of reference should be drafted, which have to adopted at a plenary meeting of the GMO panel and subsequently will have to be transmitted to the Executive Director of EFSA for approval.

Following self tasking projects will be considered for further action:

- *Post-market environmental monitoring of GM crops*. It was noticed that this issue should also be addressed in the guidance document on the risk assessment GM food/feed derived from GM crops. As a clear distinction between risk management and risk assessment of post-market monitoring of GM crops is difficult to make, it would be recommended to invite the Commission to comment on the terms of reference.
- *Safety of use of viral promoters/ instability of transgenes.* As viral promoters are used in several of the GMOs for which a market authorisation is sought, this is considered as an urgent activity and a working group will be set up.
- *Post-market human/animal health monitoring of GM food/feed.* Recognizing that this is a very complex issue, especially in the case of commodity crops, a working group will start to identify the right questions first. The general principles of such monitoring will also be addressed in the GM food and feed guidance document.
- *Improve the approaches for allergenicity assessment of GMOs*. The purpose would be to investigate new ways of assessing (non-)allergenicity. It was suggested that it could be useful to organise a workshop on this subject in addition to the work of the GMO panel.
- *Guidelines for GM micro-organisms in food*. Guidance documents on this issue have been published by the Joint FAO/WHO Expert Consultation on Foods Derived from Biotechnology, as well as by ILSI. These documents will first be examined by the GMO panel before it could be decided if the GMO panel should undertake this self tasking.
- *Detection strategies for GMOs.* It was suggested to invite an expert from the JRC at one of the future plenary meetings to explain the criteria for GMO detection. This information could be useful to decide if further guidance is needed on this issue.
- *Impact of GMOs on microbial biodiversity and function in the soil environment.* As this topic is part of the subject of the working group on post-market environmental monitoring of GM crops, the outcome of the discussions of both working groups could be collated.

The following initially proposed self tasking projects will be put on hold or deferred to a later stage as they are currently discussed within other forums or not much data are available:

- *Alternative methods for antibiotic resistance marker genes* (other markers; recombination systems to excise selectable markers and/or stack genes).
- *The potential use of new profiling technologies in risk assessment.*

- *Guidelines for medicinal GM crops.*
- *Guidelines for transgenic animals.*

The GMO panel will not deal with the initially proposed self tasking project on *co-existence of different agricultural systems: good agricultural practices for GM crops*, as this issue concerns an economic and management problem.

11. SCHEDULE FOR FUTURE PLENARY MEETINGS

In view of the anticipated workload of the GMO Panel and particularly the very short deadlines that are imposed by the legislation it was decided to have more frequent plenary meetings of one and a half day.

Following dates have been proposed: 11 December 2003 (optional), 20 – 21 January 2004, 3 – 4 March 2004, 21 – 22 April 2004 , 25 – 26 May 2004, 7 – 8 July 2004.