European Food Safety Authority

MINUTES OF THE 2ND PLENARY MEETING OF THE SCIENTIFIC PANEL ON GENETICALLY MODIFIED ORGANISMS HELD ON 4 JULY 2003 (ADOPTED ON 2 OCTOBER 2003)

AGENDA

PARTICIPANTS

GMO Panel:
Hans Christer Andersson, Hans-Joerg Buhk Howard Davies, Marc De Loose, Michael Gasson, Niels Hendriksen, Colin Hill, Sirpa Kärenlampi, 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:
Maud Feuillet (administration GMO Panel), Suzy Renckens (scientific co-ordination GMO Panel)

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

APOLOGIES

GMO Panel:
Detlef Bartsch, Ilona Kryspin-Sorensen

1. WELCOME AND APOLOGIES FOR ABSENCE

The Chairman, Harry Kuiper, opened the meeting and welcomed all. There were 2 apologies for absence.

2. ADOPTION OF THE AGENDA

The agenda was adopted as proposed.

3. DECLARATION OF INTERESTS

Members were informed that in addition to the general yearly declaration of interests completed during the Inaugural Meeting, a more specific form has to be completed for each individual opinion that is issued. There were no specific interests declared.

4. MINUTES OF THE PREVIOUS MEETING

The minutes of the 1st Plenary Meeting (26 May 2003) were adopted, subject to a few changes proposed by the Panel.

5. FEEDBACK FROM THE SCIENTIFIC COMMITTEE

The Chair gave the Panel an overview of the outcome of the first meeting of the Scientific Committee (SC) held on 30 June and 1 July 2003. The Scientific Committee is composed of the chairs of the different Scientific Panels and 6 independent experts. Prof. Vittorio Silano was elected as Chair of the SC and Dr. Ada Knaap and Dr. Pierre Le Neindre were elected as Vice-Chairs. The SC will meet once a month.

The SC discussed the flow of requests for scientific advice from the Commission to EFSA. The Committee expressed the need for good interaction between the Scientific Panels and the Committee. It was agreed that questions can be put immediately to the EFSA Scientific Panels and not compulsory via the SC, but that the SC should be kept informed. The Executive Director explained that the SC will operate separately from the Panels, in the interests of European consumers. Currently, the European Commission (Interface Unit) is preparing a draft guidance document for the preparation of requests for scientific advice to EFSA. The SC proposed to set up a small working group to comment on the document.

The SC asked for feedback from the Panels on a general format for opinions expressed by the EFSA Panels and Committee - for which an EFSA proposal had been distributed - and on other possible issues to be addressed by the Scientific Committee.

The SC raised possible issues for further consideration in the area of harmonisation of risk assessment approaches or challenges in the area of food safety. It also intends to consider in more detail the issue of qualified presumption of safety, how to handle a food crisis, the need for animal experimentation, ways to improve the communication of risks to the consumer and other

stakeholders. The SC agreed to form joint working groups, composed of experts from different Panels, dealing with issues in the area of exposure assessment, quantitative risk assessment, and non-conventional products not considered as foods. The creation of other working groups will be considered at the next plenary meeting.

The Chair reported that the SC and the Executive Director had a long discussion about the issue of confidentiality and conflicts of interest. They identified the need for a guidance document on declarations of interest to be provided by the EFSA.

There was another discussion about how consumers would participate in the actions of the Panels and SC. In order to get an idea from what consumers expect from EFSA a stakeholders colloquium will be organized later this year.

6. UPPER AUSTRIA QUESTION: DRAFT OPINION

Introduction

EFSA has received an urgent request for scientific opinion from the Commission related to an 'Austrian notification of national legislation governing GMOs under article 95(5) of the Treaty'.

The Austrian notification relates to a draft Provincial Act prohibiting the cultivation of genetically modified seeds and propagating material, the use of transgenic animals for breeding purposes and the release of transgenic animals in particular for hunting and fishing purposes and a study entitled "GMO-free agricultural areas: design and analysis of scenarios and implementation steps" on which the draft is based.
EFSA is requested to provide a scientific opinion as to whether the information in the report provides any new scientific evidence, *in terms of risk to human health and the environment*, that would justify the banning of cultivation of genetically modified seeds and propagating material, the use of transgenic animals for breeding purposes and the release of transgenic animals, authorised for these purposes under Directive 90/220/EEC or Directive 2001/18/EC. In particular, EFSA is requested to comment as to whether the scientific information presented in the report provides new data that would invalidate the provisions for the environmental risk assessment under the above legislation. EFSA is not requested to comment on information that does not impact on risk to human health and the environment, in particular that relating to the management of co-existence.

During its first plenary meeting of 26 May, the Panel set up a small working group to prepare a draft opinion.

The scientific co-ordinator informed the Panel that EFSA intended to have a press briefing and press release on the opinion as this was the first scientific opinion to be issued by EFSA. Moreover, in order to communicate the opinions to a larger public, EFSA has decided that each opinion should be accompanied by a summary that should be translated to German and French for publication on the website.

Discussion

The chairman thanked the working group, consisting of members of the Panel, for preparing the draft in very short time and therefore being able to adopt an opinion within the imposed time frame.

The draft opinion was presented to the other Panel members, followed by an intense discussion and some amendments to the document.

As a main conclusion the opinion states that:

- the scientific information presented in the report provided no new data that would invalidate the provisions for the environmental risk assessment established under Directive 90/220/EEC or Directive 2001/18/EC.
- the scientific information presented in the report provided no new scientific evidence, in terms of risk to human health and the environment, that would justify a general prohibition of cultivation of genetically modified seeds and propagating material, the use of transgenic animals for breeding purposes and the release of transgenic animals, authorised for these purposes under Directive 90/220/EEC or Directive 2001/18/EC in this region of Austria.

Panel members were content with the scientific content of the opinion. They stressed the importance of applying a case by case assessment to each individual GMO. They did however express concerns as to whether it would be clear why the Panel did not address issues which could be of greater concern to the public, as the issue of co-existence of GM crops and non-GM crops which is an important agricultural issue but a matter of risk management.

Members felt that the Panel should also be consulted on the text of the summary (in 3 languages) of the opinion and the press release to ensure that the correct message was communicated. Andy Stimpson from EFSA's Communication Department was called to the meeting to give more information on the planned press briefing. It was agreed that Harry Kuiper and Jeremy Sweet of the Panel would assist the Executive Director during this briefing of the journalists.

Adoption

The amended opinion was adopted by the Panel. There were no minority opinions. The opinion will be published on the EFSA website: http://www.efsa.eu.int/pdf/opinion_gmo_01.pdf

7. SHORT EXCHANGE OF VIEWS ON GUIDANCE DOCUMENT (FROM 6-7 MARCH 2003)

At the first plenary meeting the scientific co-ordinator informed the Panel members of the publication of the 'Guidance document for the risk assessment of genetically modified plants and derived food and feed' of 6-7 March 2003, prepared for the Scientific Steering Committee by the 'Joint Working Group on GMOs and Novel Foods' composed of members from the former SCP, SCF and SCAN and ad hoc experts. The new GMO Panel members were invited to consider this guidance document and comment observations.

The experts indicated that, although small amendments could be proposed, this document is fully in line with the current state of scientific knowledge in risk assessment of GMOs and therefore, in view of harmonisation, should be used as guidance document.

The document will be updated within the framework of the recently adopted new regulation on genetically modified food and feed, which requires EFSA to publish detailed guidance to assist the applicant in the preparation and presentation of the application before the date of application of the regulation.

8. DISCUSSION ON WORKING PROCEDURES AND SETTING UP OF WORKING GROUPS

The chairman made proposals for a working procedure for the evaluation of GMO applications. During the last meeting 4 different 'expertise' groups were set up – (1) molecular characterization, (2) comparative analysis, (3) food & feed safety, toxicology, nutrition and (4) environmental issues - and the members indicated for which group(s) they would have the appropriate expertise. All of these groups will work in parallel to assess the relevant parts of the dossier whereas one expert will be in charge of the overall co-ordination.

During the discussion, areas of expertise were identified that could require strengthening by involving experts from other Panels such as the FEEDAP Panel (Additives and products or substances used in animal feed), the PPR Panel (Plant health, protection products and their residues) and the NDA Panel (Dietetic products, nutrition and allergies) or ad hoc experts with particular expertise in fields such as entomology, exposure assessment and bioinformatics. Some proposals for additional experts were already made, though there was general agreement that on a case by case basis, in light of the kind of question the Panel will be dealing with, further expertise will have to be sought.

9. DISCUSSION ON SELF TASKING

The participants discussed the possibility of self tasking, i.e. the Panel raising questions itself, and had a discussion to identify areas where there could be an immediate or future need to address scientific questions. A proposal made by the former joint Working Group on GMOs and novel foods was used as starting point. The following possible issues were identified:

- Risk assessment of antibiotic resistance marker genes and alternative methods
- Safety of use of viral promoters (e.g. activation of silent genes) / instability of transgenes
- Post-market monitoring GM food/feed
- Post-market monitoring GM crops
- Assess the potential use of new profiling technologies in risk assessment
- Improve the approaches for allergenicity assessment of GMOs
- Guidelines for medicinal GM crops
- Guidelines for GM micro-organisms in food
- Guidelines for GM micro-organisms in the environment (e.g. bio-fertilizers)
- Detection strategies for GMOs

For several of the proposed topics a rapporteur was identified who will prepare a draft background document to initiate the work. In relation to the first topic on antibiotic resistance marker genes and alternative methods, a first working group meeting was scheduled for 28 August 2003.

10. GENERAL INFORMATION FROM EFSA

10.1. Draft work programme: document to Management Board

The Panel received an updated document of the draft working program of the Panel that was prepared for the Management Board. There are currently no new questions to the Panel.

10.2. Decision concerning access to documents

The Panel received a copy of the Decision by the Management Board (doc. MB 18.06.2003 – 5) concerning Access to documents.

11. ANY OTHER BUSINESS

The Panel briefly discussed the EFSA proposal on format for scientific opinions (doc. EFSA/GENERAL/2). Two observations were made: (1) there should be the possibility for scientific reports to be published separately from an opinion and (2) it was not clear if the 'Approved by' before the names of the Panel members would also allow adding names of experts who agree with the opinion but are unable to attend the plenary meeting where the opinion is adopted.