European Food Safety Authority

MINUTES OF THE 1ST PLENARY MEETING OF THE SCIENTIFIC PANEL ON GENETICALLY MODIFIED ORGANISMS (GMO PANEL) HELD ON 26 MAY 2003

PARTICIPANTS

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

EFSA:
Geoffrey Podger[1] (executive director), Jochen Brodersen[1] (finance), Maud Feuillet (administration GMO Panel), Suzy Renckens (scientific co-ordination GMO Panel)

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

APOLOGIES

GMO Panel :
Hans-Joerg Buhk[2], Pere Puigdomenech[2]

I. GENERAL INAUGURAL MEETING (MORNING SESSION)

The Executive Director welcomed all attending the meeting. The objective of the first part of the meeting was to brief the Members of the Scientific Panels and Committee on their role, the role of EFSA and the joint interrelationship with other European Institutions and with National Authorities. The first session was intended to provide opportunities for everyone to participate in the discussion. It was hoped that there would be strong and lively interaction between EFSA and members of the Scientific Committee and Panels on all future dealings, as this was the way to build mutual confidence and make best use of the very considerable scientific expertise which was available.

The Executive Director stressed that EFSA wished to build on the many achievements of the previous scientific committee system. Equally EFSA had not been created to simply replicate the previous system but to make innovations in a number of key areas. In particular, there was a need:

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[1] Attending morning session only

[2] Present at the general inaugural meeting on 22 May 2003

(i) to develop and make open and transparent the science of risk assessment. The Scientific Committee would have a particular role in this;

(ii) to provide greater opportunity for stakeholder participation in the risk assessment process and the delivery of a final opinion;

(iii) to provide public and realistic timeframes for work which was undertaken and, except in exceptional circumstances, to adhere to these;

(iv) to engage, in liaison with national authorities, in more timely and meaningful communication of risk assessments. This would in itself require considerable dialogue between EFSA and its Scientific Committee and Panels;

(v) to ensure that the best expertise available was used. The Scientific Committee and Panels should be ready to form Working Groups or use other means to obtain the external expertise they needed.

In concluding his opening remarks, the Executive Director took the opportunity of congratulating the members of the Scientific Committee and Panels on their selection by the EFSA Management Board. The standard of selection had been high and many very good candidates had unfortunately to be disappointed, although it was hoped there might be opportunities for them to participate in Working Groups. EFSA staff very much looked forward to working with and supporting those present.

The participants were then given practical information on the internal rules of procedures (by Jochen Brodersen) and on the role of the Interface Unit of the Commission (by Michael Walsh).

II. 1ST PLENARY MEETING OF THE GMO PANEL (AFTERNOON SESSION)

1. WELCOME, APOLOGIES FOR ABSENCE

The scientific co-ordinator welcomed the participants and congratulated the panel members with their nomination on the GMO Panel. All members of the panel were present, except for two members that sent apologies.

2. ADOPTION OF THE AGENDA

The agenda was adopted without amendment.

3. TOUR DE TABLE: INTRODUCTION OF MEMBERS

All participants briefly introduced themselves. A short resume of the CV of each member was included in the documentation package. It was noted that information on the members would be placed on the EFSA website (http://www.efsa.eu.int)

The panel members were given the opportunity, before and during the meeting, to propose candidates for the positions of Chair and Vice-Chair of the panel and to provide information in support of their proposal.

4. ELECTION OF THE CHAIR AND VICE-CHAIRS

Dr. Harry Kuiper (NL) was elected as Chair of the panel and Dr. Jeremy Sweet (UK) and Prof. Fergal O'Gara (IRL) were elected as Vice-Chairs.

5. DECLARATIONS OF INTEREST/CONFIDENTIALITY/INDEPENDENCE

The participants were invited to submit their declarations of interest, confidentiality and independence to the administrative secretary.

6. WORK PROGRAMME

The scientific co-ordinator gave a brief introduction on the mandate of the panel and the expected work programme.

Under Article 18 of the Decision concerning the establishment and operations of the Scientific Committee and Panels, adopted by the Authority's Management Board on 17.10.2002, the mandate of the Panel is set out as follows: 'The Scientific Panel on Genetically Modified Organisms will deliver opinions on scientific questions relating to genetically modified organisms as defined in Directive 2001/18/EC, such as micro-organisms, plants and animals, relating to deliberate release into the environment and genetically modified food and feed including their derived products'. Thus, it was noted that the range of questions that can be put to this panel is very wide, ranging from environmental issues to food safety for the consumer. Questions can be related to GMO authorisation dossiers introduced under Community legislation (e.g. directives 90/220/EEC and 2001/18/EC, regulation 258/97 and the future regulation on genetically modified food and feed) or can be of more general nature. Questions can be raised by the Commission, the European Parliament or a Member State, and also by EFSA itself (e.g. the GMO Panel could propose self tasking in an area of key interest).

6.1 DRAFT QUESTIONS TO THE PANEL

UPPER AUSTRIA CASE

EFSA has received a draft question from the Commission related to an 'Austrian notification of national legislation governing GMOs under article 95(5) of the Treaty'. The issue was introduced by the Commission services.

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.

Regarding the urgency of the matter, the Commission requesting an opinion from EFSA by 15 July 2003, the panel decided to set up a small working group to deal with this question.

GUIDANCE DOCUMENT

At the meeting of the EFSA Advisory Forum of 14 May 2003 in Athens, members expressed the need to harmonise the existing guidelines for risk assessment of GMOs. While recognizing that there is a general consensus on the risk assessment of GMOs, it was also illustrated that there are specific aspects for which national authorities have a different approach. It was agreed by the Advisory Forum that the GMO Panel should take into account the different guidance documents while drafting future guidelines and that member states should be invited to make comments on a draft opinion. According to the proposal for new regulation on genetically modified food and feed , EFSA has to publish detailed guidance to assist the applicant in the preparation and presentation of the application before the date of application of the regulation.

The scientific co-ordinator informed the new panel members of the recent publication of the new '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. Several members of the different EFSA panels have contributed to this exercise that was started 3 years ago and involved the consultation of interested parties through the internet. The GMO Panel members that have been involved in the past explained that this document is fully in line with the current state of scientific knowledge in risk assessment of GMOs. The new GMO Panel members were invited to consider this guidance document and comment observations by the next plenary meeting.

6.2 EXPECTED GMO AUTHORISATION DOSSIERS

The scientific co-ordinator provided the panel with the state of the art of GMO authorisation dossiers introduced under Community legislation (2001/18/EC and regulation 258/97) for which questions could be referred to the panel on a case by case basis. No question related to a dossier has been put to the panel so far. Because of the current situation in Europe, in the context of new legislation on genetically modified food and feed and on the traceability and labelling of GMOs enters into force, it is difficult to make an estimate of the future workload of the panel.

6.3. EXCHANGE OF VIEWS ON SELF TASKING

The participants discussed the possibility of self tasking. Some suggestions for scientific questions that could be dealt with were already made by the former joint Working Group on GMOs and novel foods. It was agreed that self tasking questions will be discussed at the next plenary. Members were invited to reflect on the possible questions and to send suggestions to the secretariat, preferably already accompanied by a solid background justification.

7. ORGANISATION OF WORKING GROUPS

In view of evaluation of future dossiers different 'expertise' groups were identified within the panel that could deal with specific parts of a dossier. It is expected that the panel will need additional expertise from colleagues from other panels and external experts on specific issues (e.g. feed matters, natural toxins, nutrition, entomology etc.). At the next plenary meeting, the organization of working procedures will be discussed, and names of additional experts will be identified.

8. SCHEDULE OF MEETINGS FOR 2003

Next plenary meetings of the GMO Panel were scheduled for 4 July, 2 October and 25 November 2003.

9. ANY OTHER BUSINESS

The scientific co-ordinator informed the panel that the former Commission archiving system CIRCA can no longer be used. EFSA will employ a new Document Management System (DMS) that currently is being set up and will be implemented in the future.