MINUTES OF THE 2ND PLENARY MEETING OF THE SCIENTIFIC PANEL ON PLANT HEALTH, PLANT PROTECTION PRODUCTS AND THEIR RESIDUES

HELD IN BRUSSELS ON 7 OCTOBER 2003

(adopted on 29 October 2003[1])

AGENDA

PARTICIPANTS

Members of the PPR Panel

Mr. J. BOESTEN, A. BOOBIS, A. HARDY (Chair), A. HART, R. LUTTIK, Mrs. K. MACHERA, Mr. M. MARONI, D. Mc GREGOR, O. MEYER, A.MORETTO, Mrs E. PAPADOPOULOU-MOURKIDOU, K. SAVOLAINEN, A. SCHAEFFER, W. STEURBAUT, Mrs. D. TSIPI-STEFANITSI and C. VLEMINCKX.

Apologies

Mr. H. KOEPP, E. PETZINGER.

EFSA

Mrs. M. DUNIER-THOMANN and Mr. C. LAURENT

European Commission

Mr. M. WALSH[2] (Interface Unit, DG Health and Consumer Protection)

[1] By written procedure.

[2] Part of the meeting.

1. WELCOME, APOLOGIES FOR ABSENCE

The Chair opened the meeting and welcomed a new member of EFSA staff to the PPR Panel, Mr. C. LAURENT, a genetic toxicologist coming from the University of Liege (Belgium) and former expert at the Scientific Committee on Cosmetic and Non-Food Products in DG SANCO. Apologies for their absence were received from H. KOEPP and E. PETZINGER.

2. ADOPTION OF THE AGENDA

The agenda was adopted with changes in the order of items as the Chair had to leave on mission in the afternoon; he was replaced by the vice-Chair.

3. FEEDBACK ON THE EFSA OPINION ON CONFLICT OF INTEREST

The Chair of the Scientific Panel PPR explained the outcome of the discussions of the Scientific Committee on the issue of conflicts of interest. For transparency reasons, members that declare an interest which excludes them from contributing to and adopting a specific opinion, will be 'marked' with an asterisk in the list of Panel members at the end of the opinion. The Chair, agreed that H. KOEPP should not contribute to the development and adoption of the opinion on azinphos-methyl as a result of a conflict of interest (he had explained that he was involved in an earlier tripartite meeting with the notifier and the Commission).

EFSA legal service is finalizing a code of conduct for all panels to provide guidance on how to deal with a declared interest. It was agreed that members of the Panel will be invited to fill the form on declaration of interest for each new dossier.

4. FEEDBACK FROM DISCUSSIONS IN THE SCIENTIFIC COMMITTEE

4.1 Guidelines in preparation: self tasking

The Chair informed the Panel members that EFSA wishes to establish internal procedures for the way it will deal with requests from the European Parliament, the Commission, the Member States and for self-tasking. A draft Commission guideline for the preparation of requests for scientific opinions by the EFSA is under preparation with contribution of the Scientific Committee. The prioritisation of the requests received by EFSA will be discussed in the Scientific Committee. The Chair will circulate the work programme of the Scientific Committee when available and will give some extended feedback in the next Plenary meeting on self-tasking.

4.2 Adoption of minutes by written procedure

A written procedure will be used for the adoption of the minutes of all the plenary meetings, as agreed in the Scientific Committee. The draft will be circulated by the secretariat and 10 working days will be given to the Panel members to comment. As a quorum is needed, all members are asked to send by email their agreements on the final text when circulated by the secretariat.

4.3 New EFSA template for scientific opinions

The Chair informed the Panel that the Scientific Committee discussed on 27-28th August a proposal for a general format of all scientific opinions of the Authority and which was approved by the executive Director. The new EFSA template was distributed to all Panels members and used to prepare the two current draft opinions to be adopted by the PPR Panel.

General Structure

A scientific opinion must at least include the background and terms of reference of the request to the EFSA, as provided by the client (e.g. Commission); it must include an assessment chapter addressing the questions posed to the EFSA, how the information was evaluated and which issues were considered of key-relevance for the opinion. Furthermore, the opinion should include a section with the conclusions and, if any, the recommendations, and it should list all documentation made available to the EFSA by the client and any references cited in the opinion.

Summary

A clear summary should summarise which questions were asked, which information was evaluated, the key issues that were addressed by the opinion, and the conclusions and, any, recommendations of the assessment. The EFSA Communication division will be available to assist the Panel members with the wording of a summary that is informative for any stakeholder, both the technical and non-technical reader. The Panel would also automatically adopt the contents of the summary when adopting the opinion. The text of the English summary has to be considered as the definitive text; the French and German translations thereof should include a declaration that the English summary is the definitive text. The translation of the Summary in French and German will be supervised by a native speaker of the Panel.

Listing of names of members of the Scientific Panel

The opinion should contain a list of all the members of the Scientific Panel. The opinion is considered to be a collective opinion of the Scientific Panel. For transparency reasons, any members that have a specific declared interest, which excludes them from the adoption of an opinion, will be 'marked' with an asterisk.

Listing of names of ad hoc experts

In a separate section, the Panel will acknowledge the preparatory work of *ad-hoc* experts that contributed to the preparation of the draft opinion. According to the legal officer of EFSA the listing names of both members and *ad hoc* experts will cause no problems of individual liability as the legal responsibility remains with EFSA provided that it concerns the work done by the members on EFSA's behalf.

Minority opinion

In the case of a minority opinion, a paragraph will be added according to the common rules of procedure (Article 19 of Decision MB 17.10.2002–3.adopted[3]: "*The opinions of the Scientific Committee and Panels within the meaning of Article 29 of the Regulation, shall include any minority opinions. Minority opinions shall be attributed to their authors and shall include supporting argumentation.*").

[3] See: http://www.efsa.eu.int/pdf/decision_panels_mb_04_en.pdf

5. POSSIBLE ADOPTION OF THE OPINION ON MEPANIPYRIM

The rapporteur prepared a draft opinion on the question concerning whether or not a threshold mechanism for tumour formation can be assumed for the liver tumours found in rats and mice exposed to mepanipyrim, which had been discussed and amended in two meetings of the Working Group (WG) Toxicology. The opinion was finalized at the plenary meeting on 7th October and was circulated for adoption by written procedure (in 10 working days). Members were reminded that a quorum of agreements of the Panel members was required to be able to adopt an opinion.
The opinion will be then published on the EFSA website[4] as "The EFSA Journal (2003) 4,1-14."; the summary translated into French and German will also be put on the website.

6. POSSIBLE ADOPTION OF THE OPINION ON AZINPHOS-METHYL

Two rapporteurs had prepared a draft opinion on the separate questions on the impact of azinphos-methyl on non-target arthropods and birds, which were discussed and amended in two meetings of the WG Ecotoxicology. Two *ad hoc* experts had been invited to joint the WG. The opinion was finalized at the second plenary meeting on 7th October and the opinion was circulated for adoption by written procedure. A sentence explaining that "the EFSA Management Board agreed not to accept new data submitted by the notifier after the question had been asked to EFSA and would not be taken into consideration to produce the opinion" was inserted in the text of the opinion.
The opinion will be published on the EFSA website as "The EFSA Journal (2003) 5 or 6,1-21"; together with the summary translated into French and German.

7. WORK PROGRAMME AND SCHEDULE OF MEETINGS FOR END OF 2003 AND 2004

M DUNIER-THOMANN and M.WALSH had met with an administrator from DG SANCO E1 on 6th October. A confidential draft document was distributed to the Panel members to provide an overview of the possible requests from the Commission for the scientific advice of the PPR Scientific Panel. In principle the next set of questions in toxicology should be raised in the coming months by the Commission. Consequently, half a day on 1 December 2003 afternoon (before the plenary on 2nd December) was reserved for a meeting of the WG Toxicology, in case the new questions should be available by that time together with the related documents[5]. Possible rapporteurs were identified.
Much more requests will be sent by the Commission early 2004, more likely in the toxicology area. More precise information should be available after the next WG Evaluation of the DG SANCO on 6-7th November and given at the next plenary meeting.
EFSA, which is in charge of the coordination of the peer review of the re-evaluation programme of the second list of 52 active substances, could start to self-task the PPR Panel with questions by the end of 2003.
The Commission was also asked to clarify quickly the timing of possible requests to the EFSA PPR Panel on the Guidance Documents currently under preparation as well as on the revision of Annex II and III of the Directive 91/414/EEC.

[4] See: http://www.efsa.eu.int/p_plant_en.html

[5] WG Tox cancelled afterwards (documents not available on time).

Dates of the plenary meetings
The future meetings of the PPR Panel have been agreed as: 2 December 2003, 27th January, 16 th March, 11 th May, 30 th June, 14 th September, 28 th October and 14 December 2004.

Dates of the Toxicology Working Group meetings
Some WG Tox. meetings were reserved for 2004: 13 th January, 17 th February, 9 th March, 27 April 2004, more dates will be selected at the next plenary meeting for other WG.

8. FEEDBACK FROM THE WORKSHOP " Risk Assessment- Risk Management" 3-5 SEPTEMBER 2003 (THE NETHERLANDS)

A. HART was the coordinator of an European workshop on the interface between Risk Assessment and Risk Management, which took place in Noordwijkerhout (The Netherlands), funded by DG Research. T. HARDY, M. MARONI, M. WALSH, most of the EFSA Scientific Coordinators, including M. DUNIER-THOMANN attended it.

As the outcomes of this workshop could be relevant for a further consideration in EFSA, more details will be given in the next plenary meeting in December.

9. ANY OTHER BUSINESS

The Scientific Committee of EFSA agreed to create a Working Group on a Uniform Approach for Genotoxic and Carcinogenic substances (GENTOX). K. SAVOLAINEN (Vice-Chair) was invited to become member of this WG (one member per Panel). GENTOX WG is foreseen to meet for up to one year to complete its work, with a limited number of participants, including experts from DG SANCO's Scientific Committees dealing with non-food issues.