MINUTES OF THE 17TH PLENARY MEETING OF THE SCIENTIFIC PANEL ON PLANT HEALTH, PLANT PROTECTION PRODUCTS AND THEIR RESIDUES

HELD IN PARMA ON 22-23 MARCH 2006

(Adopted by written procedure on 07 April 2006)

Agenda

#	Items
1.	Welcome, apologies for absence, declaration of interests
2.	Adoption of the agenda
3.	Adoption of the opinion on dichlorvos
4.	Adoption of the opinion on NOEC mammals
5.	Adoption of the opinion on AOEL Guidance Document
6.	Adoption of the opinion on the summary opinion in toxicology
7.	Feedback on the opinions in preparation on the revision of Annexes II and III to Dir. 91/414/EEC: Residues, Analytical methods, Physical and chemical properties
8.	New development on the question from PRAPeR on consumer exposure/residues
9.	Miscellaneous: • Feedback from the Scientific Committee and WGs o WG Exposure: feed-back on draft on uncertainties in dietary exposure assessment o Position paper on the functioning of the EFSA's SC and Panels • DG RDT 7th Framework programme • Provisional calendar of Plenary meetings for the next PPR Panel

PARTICIPANTS

Members of the PPR Panel

Mr. D. BARCELÒ-CULLERES, Mr. R. BLACK, Mr. J. BOESTEN, Mr. A. HART, Mr. H. KOEPP*, Mr. R. LUTTIK, Ms K. MACHERA, Mr. O. MEYER, Mr. A. MORETTO, Ms E. PAPADOPOULOU-MOURKIDOU, Mr. E. PETZINGER*, Mr. K. SAVOLAINEN, Mr. J. STENSTRÖM and Mr. W. STEURBAUT.

Mr. R. SHORE was invited to answer questions on the opinion on NOEC mammals.

* part-time

EFSA

Ms. M. DUNIER-THOMANN, Mr. B. BERGER, Ms. C. FUELL, Ms. A. DE BLOCK and Ms. G. BOSCHETTO. H. REICH and D. BROCCA from the PRAPeR unit joined the meeting for agenda item 8.

European Commission

Mr. X. PAVARD, (DG SANCO, O3).

1. WELCOME, APOLOGIES FOR ABSENCE

The vice-chairman, Mr. K. SAVOLAINEN welcomed the participants. Apologies had been received from Mr. A. BOOBIS, Mr. A. HARDY, Mr. M. MARONI, Mr. D. MC GREGOR, Mr. A. SCHAEFFER, Ms. D. TSIPI-STEFANITSI and Ms C. VLEMINCKX. Since there was no quorum given (only 13 Panel members present) the opinions were adopted in principle, but a final adoption by written procedure will be necessary.

2. ADOPTION OF THE AGENDA

The agenda was adopted without changes. Declarations of conflicts of interests were made previously by Mr. D. McGREGOR on dichlorvos and by Mr. M. MARONI on the AOEL Guidance document.

3. ADOPTION OF THE OPINION ON DICHLORVOS

A previous draft of the opinion has been circulated to all members of the Panel, and comments from several members of the Panel have been received, included and discussed during the Working Group meeting on 21/22 March 2006. Based on this, a new version has been produced. The rapporteur presented the overall structure and the summary of this new version. The Panel then discussed the summary and the body of the text, in particular regarding the amount of existing studies demonstrating evidence or not of mutagenicity of dichlorvos and the carcinogenic responses of the forestomach, also in relation to the specific exposure scenario in that organ. Based on the discussion, the text was clarified.

The chairman thanked the rapporteurs for the considerable work done. The final draft was accepted in principle, and will be circulated by the secretariat for adoption by written procedure by

all Panel members on 1 April. The opinion will then be published on the EFSA web as soon as possible.

4. ADOPTION OF THE OPINION ON NOEC MAMMALS

The opinion was presented by one of the rapporteurs. The request was formally accepted during the 13th PPR Panel Plenary meeting on 15-16 September 2005 and was discussed in four Working Group meetings. The request consists of two questions:
Q1: The ecotoxicological relevance of observed parameters in long-term toxicity studies on mammals in the field, and what is the most appropriate parameter and the most appropriate study to assess the long-term risk to mammals.
Q2: How the assessment endpoints considered in Question 1 can be used in an appropriate refined assessment of long-term risk to mammals, including interpretation of the magnitude of effects in such studies.
A final draft version had been sent to all Panel members on 07 March 2006 for commenting. The proposals and comments received had been comprehensively discussed in the preceding Working Group (21-22nd March) and included and/or dealt with in the opinion. After a general discussion, detailed studying of section 2.3 (the section that had undergone most changes) and inclusion of some further editorial comments made by the Panel members, the opinion was in principle adopted by the PPR Panel. The EFSA Secretariat will circulate this version, asking the PPR Panel members to confirm the adoption by written procedure by 06 April 2006. The opinion will then be published on the EFSA web as soon as possible.

5. ADOPTION OF THE OPINION ON AOEL GUIDANCE DOCUMENT

A new draft has been produced based on comments received on a previous version after circulation to all Panel members, and the consequent discussion in the Working Group on 21/22nd March. The rapporteur presented that new version and gave also some background information on the Guidance Document itself. Main general issues addressed in the opinion are the question on studies involving humans, the question of bystanders, the fact that the document should focus on issues specific to AOELs, and the importance of addressing the potential role of physiologically based pharmacokinetics in this Guidance Document. In addition, a series of more specific comments have been listed.
The Panel then discussed the draft opinion, the issues of general use of human data, bystanders as well as the concept of physiologically based pharmacokinetic modelling were discussed. The text was clarified, the list of keywords was amended. In addition, some small modifications of the summary were agreed. The opinion was in principle adopted by the PPR Panel, the secretariat will circulate it for a formal adoption by written procedure by 6th April and published soon after.

6. ADOPTION OF THE OPINION ON THE SUMMARY OPINION IN TOXICOLOGY

A previous version has been circulated to all Panel members. Comments received have been included and formed the basis of the discussion during the meeting of the Toxicology Working Group on 21/22nd March. Consequently, a new version had been elaborated. The rapporteur

presented the opinion, emphasising that this opinion is meant to summarise issues which have been learned and which are likely to be of general relevance for any future work in the field of human toxicology of pesticides. The Panel then discussed the opinion more in detail, including a discussion of the general level of detail which should be provided. Several modifications and clarifications of the text and the summary were agreed, including the way to handle abbreviations. This was followed by a more general discussion if and how the opinion should refer to the work on genotoxicity of the Scientific Committee. The Panel decided that the rapporteur should introduce some slight modifications taking account of the concerns raised. The opinion was then agreed in principle by the Panel and will be adopted by written procedure by 6th April and published soon after.

7. FEEDBACK ON THE OPINIONS UNDER PREPARATION

Revision of Annexes II and III of Directive 91/414/EEC

The PPR Panel officially adopted the request for an opinion on the revision of the Annexes II and III of the Directive 91/414/EEC in the area of residues, physico-chemical properties and analytical methods during its Plenary meeting on 14-15 December 2005. Two Working Group meetings have taken place so far, the next one is foreseen for 4-5 April 2006. An adoption of the opinion is envisaged for 17-18 May 2006.

- **Physical chemical properties**

The rapporteur presented the current version of the opinion, in particular its structure and the type of comments which are currently under discussion. Comments from WG Members have been received and a new draft will be available for discussion at the next meeting of the WG on 4-5 April 2006. The members of the Panel discussed the approach, also with a view to the other related opinions on analytical methods and residues. The issue on how to refer to methodologies agreed by other international institutions (e.g. SETAC, OECD) was discussed. The importance of several endpoints for the risk assessment as such was highlighted.

- **Analytical methods**

The rapporteur presented the current version of the opinion. Several issues are under particular discussion, such as the necessary definitions and the part on mass spectrometry. Some comments have been received; other participants of the WG still have to provide comments. Based on these comments, the rapporteur intends to provide a new version of the opinion for the next meeting of the Working Group on 4-5 April 2006. The Plenary then discussed the approach presented, in particular with regard to its effects on the other related opinions (e.g. analytical methods used pre and post-authorisation).

- **Residues**

The rapporteur presented the current version of the opinion. To clarify outstanding questions of understanding, the Working Group has convened a special meeting with the author, whose willingness to attend that meeting was greatly appreciated. That meeting helped to clarify numerous outstanding issues. The rapporteur further highlighted that the documents contain a lot of new material, that it proposes a combination of Annexes II and III into one paper, and that, similar to the other questions, definitions and terminology will need to be

addressed. Finally, the rapporteur presented the way in which the comments made so far could best be addressed.

- **General aspects of all three opinions related to the revision of Annex II and III**

The general question on how to address the issue of definitions and terminology was discussed with a view to a harmonised approach in the three opinions. It was recalled that every subgroup should make a list of terms to be defined (glossary document to be found on the extranet for everybody to consult and to complete). This could then be addressed in the general part of the opinions. It was generally recalled that the next overall Working Group on the Annex II and III will take place on 4-5 April 2006.

8. NEW DEVELOPMENT ON THE QUESTION FROM PRAPER ON CONSUMER EXPOSURE/RESIDUES

H. REICH and D. BROCCA explained the decision of the PRAPeR Unit not to re-submit the request for an opinion concerning the choice of a methodology to assess the safety of EU MRLs to the current PPR Panel and postpone it to the beginning of the term of the new Panel in June. When the question was presented at the 16th Plenary meeting of the PPR Panel, the PRAPeR Unit was asked to rephrase the question and to provide the Panel with a document to be used as a starting point for an opinion. Thus, the PRAPeR Unit is currently collecting, updating and compiling information concerning consumption data and habits in EU Member States in order to facilitate the work to be carried out by the Panel. The terms of reference of the question will be changed but will still deal with the choice of the most appropriate methodology to perform exposure assessment exercises, not only in the framework of establishment of Annex III to Regulation (EC) No. 396/2005 but also for the assessment of the safety of the MRLs to be compiled in Annex II to this Regulation. It was discussed if and how this work could benefit from a current initiative of the exposure Working Group under the Scientific Committee. With a general view to new questions to be asked, the importance of co-ordination to avoid overlap of aspects was emphasised.

9. MISCELLANEOUS

- **Feedback from the Scientific Committee and WGs**

WG Exposure: Mr. A. HART gave an overview on the main issues currently discussed within the WG Exposure on 20-21st March, on the draft opinion on uncertainty in dietary exposure assessment. The draft together with a first set of comments and answers will be circulated by the Scientific Committee in the last week of March, more detailed comments will be requested to all Panels by end of April, as the WG Exposure will meet 15-16th May to finalise the opinion and adopt it at the SC Plenary meeting 31st May.

Position paper: The Scientific Committee issued on 12th March a draft position paper on the functioning of the EFSA's SC and Panels, which will be discussed by the Management Board on 29th March, with proposals in particular for speeding up adoption of opinions and tools to provide recognition of the work carried out by the experts for EFSA. The Commission requested EFSA to deliver regular feed-back on the opinions adopted by the Panels, and a template for this was proposed. This issue will be discussed at the next Plenary meeting, it will be a basis for the new Panel.

- **DG RDT 7th Framework programme**

  A meeting took place between EFSA and DG RTD on 17-18th January, they requested EFSA's Panels to comment on the main indicative topics to be addressed under the 7th Framework Programme under Theme 2. It is asked that members of the PPR Panel who did not answered yet, send their comments to the secretariat, copy to the Chairman, as soon as possible, so that the SC can compile all Panels' comment in a document to be discussed at their next meeting 10-11th April.

- **Provisional calendar of Plenary meetings for the next PPR Panel**

  The date of the first Plenary meeting of the new Panel proposed: 14-15th June is not suitable for the toxicologists who will attend the 28th International Congress on Occupational Health to be held in Milan during that time. The secretariat will consider postponing the meeting to the following week.

- **Finances**

  New rules from EFSA Finance Department on pre-paid tickets will be applied with a stricter policy. An Expert Compensation Guide should be available for the first Plenary of the new Panel.

The 18th PPR Plenary meeting will take place on 17-18 May 2006 in Parma.