



**MINUTES OF THE 7TH PLENARY MEETING
OF THE SCIENTIFIC PANEL ON PLANT HEALTH, PLANT
PROTECTION PRODUCTS AND THEIR RESIDUES**

HELD IN PARMA ON 14 AND 15 SEPTEMBER 2004

(Adopted by written procedure on 8 October 2004)

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PARTICIPANTS

Members of the PPR Panel

Mr. D. BARCELLO-CULLERES, R. BLACK, J. BOESTEN, A. HARDY (Chair), A. HART, H. KOEPP, R. LUTTIK, Mrs. K. MACHERA, Mr. M. MARONI, D. MCGREGOR, O. MEYER, A. MORETTO, Mrs E. PAPADOPOULOU-MOURKIDOU, Mr. E. PETZINGER, A. SCHAEFFER, J. STENSTRÖM, W. STEURBAUT, K. SAVOLAINEN, Ms. D. TSIPI-STEFANITSI and C. VLEMINCKX.

Apologies

A. BOOBIS

EFSA

Mrs. M. DUNIER-THOMANN, S. HOFKENS, Mr. C. LAURENT, J.O. MAGRANS, D. DETKENS and Mrs M. MESNAOUI, M. DAFFERN.

European Commission

Mr. M. WALSH (Interface Unit, DG SANCO D).

1. WELCOME, APOLOGIES FOR ABSENCE

The Chair welcomed the participants, introduced the three new members of the Panel (their short *Curriculum Vitae* have been put on the EFSA website). Apologies had been received from one member.

2. ADOPTION OF THE AGENDA

The agenda was adopted without changes.

3. POSSIBLE ADOPTION OF THE OPINION ON FOCUS SURFACE WATER

The EFSA PRAPeR sector sent to the PPR Panel this general question relating to the Peer Review of the second list of active substances on the relevance of applying the “FOCUS Surface water” scenarios to calculate the predicted environmental concentration (PEC) in surface water to be used for the risk assessment of aquatic organisms for non-spray applications.

The rapporteur gave an overview of the draft opinion, prepared in Environment WGs with the help of *ad hoc* experts. Answers to a survey on dust deposition had been received from 12 member states out of the 25. The scientific discussion continued at the meeting of the WG Environment on 14 p.m./15th September. The adoption of the opinion is foreseen by end of the year.

4. ADOPTION OF THE OPINION ON FOCUS GROUND WATER

The rapporteur gave an overview of the draft opinion dealing with the comparability of the different FOCUS models, as prepared in the Environment WG meetings with the help of *ad hoc* experts. Because of the lack of consensus in EU on the subject, the EFSA PRAPeR sector requested to the PPR Panel to clarify the situation in order to improve the Peer Review of the second and third list of active substances.

The opinion was adopted and the final draft will be circulated for a last editorial check before publication on EFSA website.

5. DISCUSSION ON THE TWO OPINIONS ON METHAMIDOPHOS

5.1 Toxicology

The rapporteur summarised the outcomes of the Toxicology WG regarding the draft document discussed during the meeting held in Milan on the previous day. The scientific approach for the evaluation of the studies was welcomed and the rapporteur emphasized the relevance of the monkey data for human assessment. Some minor refinements were proposed to improve the final text. The opinion was adopted and the final draft will be circulated for a last editorial check before publication.

5.2 Ecotoxicology

The draft opinion dealing with the question in ecotoxicology (on birds and mammals) was presented by the rapporteur. This will be a substantial document, which will be used as

reference guidance for other substances. Field studies were detailed in two European countries. The discussions will continue at the next Ecotoxicology WG to be held on 7th October. The final opinion should in principle be ready for adoption at the plenary meeting on 28th October.

6. PRESENTATION OF THE DRAFT OPINION ON ALACHLOR

6.1 Question 1 on nasal turbinate tumours

The draft opinion on alachlor was presented by the rapporteur who confirmed the complex issue presented by this substance. On the basis on the extensive literature and studies analyzed, the rapporteur concluded that occurrence of a concentration of a metabolite of alachlor in the olfactory mucosa and its further metabolism to a sulphydryl-reacting, cytotoxic product induced cell proliferation and changes in gene expression. Neoplasia arises from this metaplastic or transdifferentiated tissue. Therefore, evidence in favour of a genotoxic mode of action for alachlor appears to be weak if any.

6.2 Question 2 on the relevance of metabolites

The rapporteur and the members of the PPR Panel agreed that this issue is very complex (a large number of metabolites are generated). Additional work will be done by the next Toxicology WG on 27th October. The adoption of the opinion is foreseen in principle at the PPR Panel plenary on 28th October.

7. STATE OF THE ART OF THE OPINION ON DIMOXYSTROBIN

The draft opinion on the question from EFSA PRAPeR sector sent to the PPR Panel in ecotoxicology (on fish long term toxicity) on dimoxystrobin was presented by the rapporteur. An *ad hoc* expert will be invited at discussions of the next Ecotoxicology WG on 7th October and following ones.

The adoption of this opinion is foreseen in principle on 14th December 2004.

8. NEW QUESTION: CREATION OF A RESIDUES WG

The new question recently received informally from the Commission concerns the variability factor for estimating acute consumer exposure to pesticide residues. It was discussed and accepted in principle with the restriction that the deadline of November requested by the Commission could not be met. The time constraint of the Commission is due to the presentation the EU position at a meeting of Codex Committee Pesticide Residue in March 2005. In line with current timeframe for other questions, the PPR Panel will do the best possible for an adoption at the Plenary meeting of 16th February (if and only if all the relevant documents to the question are submitted by the Commission to the WG on time). A new Residues Working Group will be created with Panel members, a rapporteur will be nominated and *ad hoc* experts will be selected and invited at the WG meetings. Dates were selected for the meetings of the Residues WG: 8th October, 25th-26th?

November (in Brussels), 15th December (in Brussels), 11th January (in Athens) and 15th February 2005 (in Parma).

9. PRESENTATION OF THE LAST DRAFT OF THE DOCUMENT “GUIDANCE ON DECLARATION OF INTEREST”

D. Detken, from the EFSA legal services, introduced the latest draft of the document “Guidance on declaration of interest”. An intensive discussion took place; the experts raised several questions regarding the rules proposed by EFSA, particularly on the chapter on “intellectual property”. EFSA legal services took note of their remarks. The Panel members will be kept informed on the date of finalization of the document.

10. FEEDBACK FROM THE SCIENTIFIC COMMITTEE, WG GENTOX AND WG EXPOSURE

The two experts representing the PPR Panel at the WGs GENTOX and Exposure of the Scientific Committee of EFSA gave a feed-back on the state of the art on the opinions in preparation.

11. FEEDBACK OF THE PPR PANEL TO THE SC ON THE REPORT ON IMPROVING THE INTERFACE BETWEEN RA-RM

A written feed-back was requested on the report of the EU funded workshop “Improving the interface between RA-RM” in 2003, more precisely on the questions raised in the note distributed to the members of the EFSA Panels, a template was circulated after the last Plenary meeting. The secretariat had received few answers by 1st September and additional contributions were requested by the Chairman, who will give the feed-back from the Panel to the next EFSA Scientific Committee. The template will be recirculated by the secretariat after the plenary meeting with the new deadline of 1st October.

12. MISCELLANEOUS

Feedback on the access to the extranet of EFSA (Document Management System)

The access to the extranet of EFSA (Document Management System) by the PPR Panel members is now functioning. The Panel members who have not yet tested their access are requested to do so by end of September in order to inform the technology (IT) department of EFSA of any remaining problems.

The next plenary meeting will be held on 28th October 2004, starting at 9h in Brussels