



**MINUTES OF THE 8TH PLENARY MEETING
OF THE SCIENTIFIC PANEL ON PLANT HEALTH, PLANT
PROTECTION PRODUCTS AND THEIR RESIDUES
HELD IN BRUSSELS ON 28 OCTOBER 2004**

(Adopted by written procedure on 24 November 2004)

AGENDA

1. Welcome, apologies for absence	p.2
2. Adoption of the agenda	p.2
3. Adoption of the opinion on alachlor	p.2
4. Discussion and possible adoption of the opinion on methamidophos in ecotoxicology	p.2
5. Discussion of the opinion on FOCUS surface water	p.3
6. State of the art on the opinion on dimoxystrobin and on the question on variability on residues	p.3
7. Presentation of the first EFSA report on the pesticide risk assessment of the active substance tribenuron	p.3
8. Comments on the final report on “Improving the interface between Risk Assessment and Risk Management”	p.4
9. Feedback from the Scientific Committee	p.4
10. Suggestions for questions in self-tasking, prioritisation	p.4
11. Miscellaneous	p.5

PARTICIPANTS

Members of the PPR Panel

Mr. D. BARCELLO-CULLERES, Mr. J. BOESTEN, Mr. A. BOOBIS, Mr. A. HARDY (Chair), Mr. A. HART, Mr. H. KOEPP, Mr. R. LUTTIK, Mr. M. MARONI, Mr. D. McGREGOR, Mr. O. MEYER, Mr. A. MORETTO, Mrs E. PAPADOPOLOU-MOURKIDOU, Mr. E. PETZINGER, Mr. A. SCHAEFFER, Mr. J. STENSTRÖM, Mr. W. STEURBAUT, Mr. K. SAVOLAINEN,

Apologies

Mr. R. BLACK, Mrs. K. MACHERA, Ms. D. TSIPI-STEFANITSI and Ms. C. VLEMINCKX.

EFSA

Mrs. M. DUNIER-THOMANN, Ms. M. MESNAOUI, Mr. H. BRUNO.

European Commission

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

1. WELCOME, APOLOGIES FOR ABSENCE

The Chair welcomed the participants; apologies had been received from four members.

2. ADOPTION OF THE AGENDA

The agenda was adopted without changes.

3. ADOPTION OF THE OPINION ON ALACHLOR

The rapporteur presented the draft opinion on alachlor finalised on 27th October at the Toxicology WG; some more amendments were discussed and added by the Panel members.

3.1 Question 1 on nasal turbinate tumours

The PPR Panel concluded that the strength of evidence suggests that a mode of action other than genotoxicity is involved in the occurrence of nasal turbinate mucosal tumours observed in rat carcinogenicity studies. While the mode of action could be relevant for humans, it is extremely unlikely that concentrations of the active metabolite would be achieved to precipitate the chain of events terminating in cancer.

3.2 Question 2 on the relevance of metabolites

The PPR Panel concluded that the alachlor metabolites 65, 54 and 25 have been adequately tested for toxicity, but the toxicity database is inadequate in the case of the soil metabolites 85, 76 and 51. The genotoxicity database also is inadequate for soil metabolites 85, 76 and 51. For metabolite 25, the PPR Panel was unable to conclude that genotoxicity testing was adequate. It was concluded that the information presented for metabolites 65 and 54 was sufficient to demonstrate that they were not relevant; a similar conclusion cannot be reached for metabolites 85, 76, 51 and 25.

The opinion was adopted with unanimity; the final draft was circulated by the secretariat after the meeting for a final editorial check before its publication on the EFSA website.

4. DISCUSSION AND POSSIBLE ADOPTION OF THE OPINION ON METHAMIDOPHOS IN ECOTOXICOLOGY

The draft opinion, dealing with a question in ecotoxicology on exposure and avoidance in birds, was discussed and modified in the Ecotoxicology/Environment WG held on 7th October. This substantial document was presented by the rapporteur, who collated 21 questions and concerns raised by the Panel members during the discussion, including the length of the opinion. A document with the answers to those questions will be circulated by the rapporteur after the meeting. It was considered premature to adopt it at this stage; consequently the discussion will continue at the next Ecotoxicology WG to be held on 25th November. The opinion should be finalized at the Ecotoxicology WG to be held on 13th December for adoption at the next plenary meeting on 14th December 2004. The European

Commission, who raised this question, was consulted during the meeting about this postponement and was in agreement with it.

5. DISCUSSION OF THE OPINION ON FOCUS SURFACE WATER

The rapporteur of the question which relates to the Peer Review of the second list of active substances (self-tasking from the EFSA PRAPeR sector) gave an overview on the draft opinion dealing with 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. This draft was amended at the Ecotoxicology/Environment WG held on 7th October with the help of *ad hoc* experts but some additional calculations are still outstanding. Discussion will continue at the next Ecotoxicology/Environment WG meetings on 25th November and 13th December.

The adoption of this opinion is foreseen at the next plenary meeting on 14th December 2004; all written comments of the Panel members should be sent to the rapporteur before.

6. STATE OF THE ART ON THE OPINION ON DIMOXYSTROBIN AND ON THE QUESTION ON VARIABILITY OF RESIDUES

6.1 Dimoxystrobin

The rapporteur of this draft opinion on the long term toxicity of dimoxystrobin on fish (question in ecotoxicology raised by the EFSA PRAPeR sector) presented the text prepared with the help of an *ad hoc* expert. A new draft will be prepared for the next Ecotoxicology/Environment WG on 25th November and finalized at the following WG on 13th December. The adoption of this opinion is foreseen on 14th December 2004.

6.2 Variability factor for estimating consumer exposure to pesticide residues

A new Residues Working Group was created to answer the question from the Commission on the variability factor for estimating acute consumer exposure to pesticide residues. This WG met on 8th October for the first time. The rapporteur presented the state of the art of the discussions, essentially on the key paper from D. Hamilton (2004). The discussion will go on at the next WG held in Brussels on 19th November and 4 *ad hoc* experts will be invited, including statisticians. Further meetings of the Residues WG are scheduled for 15th December and 11th and 12th (a.m.) January 2005 (in Athens), 16th February and the adoption of the final opinion is in principle foreseen on 16th February 2005.

7. PRESENTATION OF THE FIRST EFSA REPORT ON THE PESTICIDE RISK ASSESSMENT OF THE ACTIVE SUBSTANCE TRIBENURON

H. BRUNO, the scientific coordinator of the EFSA PRAPeR sector in charge of the Peer Review of the second list of active substances, presented to the PPR Panel the first scientific report on the conclusion of EFSA on the risk assessment of tribenuron. Five

further reports should follow by end of 2004 among the 52 active substances of the second list.

A new section under “Science” will be created soon on the EFSA website to host those reports.

8. COMMENTS ON THE FINAL REPORT ON “IMPROVING THE INTERFACE BETWEEN RISK ASSESSMENT AND RISK MANAGEMENT”

The Chairman will give the next Scientific Committee general feed-back from the PPR Panel on the report of the 2003 EU funded workshop “Improving the interface between RA-RM”. Members of the PPR Panel who have not yet sent their written comments were asked to do so by 15 November 2004.

9. FEEDBACK FROM THE SCIENTIFIC COMMITTEE

The Chairman informed the PPR Panel that in 2005 (and then every 5 years) EFSA will be evaluated by an external contractor (to be recruited by EFSA early 2005), according to Article 61 of regulation 178/2002. A document, presented at the EFSA Management Board on 14 September 2004, containing a list of 11 questions to be raised was distributed; the Panel members were asked to comment on this list (written comments to be sent to the Chairman copied to the secretariat).

The secretariat also circulated a request from the Scientific Committee on a template prepared by the Exposure WG. Written comments were requested by 15th November on the creation of a data base on food consumption.

The DG RTD of the Commission is preparing the 7th Framework Programme. The Chairman suggested preparing some proposals for the next Plenary meeting.

10. SUGGESTIONS FOR QUESTIONS IN SELF-TASKING, PRIORITISATION

H. BRUNO explained that the EFSA PRAPeR sector will soon send officially two new questions in the sector of ecotoxicology arising from the Peer Review of active substances of the second list; one on the appropriateness of the approach on acute risk for birds in dietary exposure and the other one on the chronic risk assessment in fish. More precise terms of reference will be prepared for the next Ecotoxicology/Env. WG on 25th November.

The Chairman reminded the Panel members that they could also self-task the Panel with questions on issues of European concern in the risk assessment of pesticides; suggestions are requested for discussion at the next PPR Panel plenary meeting on 14th December.

11. MISCELLANEOUS

The PPR Panel members were informed that the secretariat of the Panel will move permanently to Parma in the first half of November 2004 and be joined by a new secretary (part-time) Maud Pâques. The present EFSA electronic addresses will remain the same but the telephone numbers may change next year.

The Chairman had received 14 replies to his request for traveling experiences of experts when attending meetings in Parma. In discussion it was requested that shuttles from/to airport should be provided by EFSA to experts attending a meeting in Parma.

The next plenary meeting will be held on **14th December 2004** (starting at 9h) in Brussels. The Chair reminded Panel members of the essential need for a quorum to adopt three opinions.