



**MINUTES OF THE 6TH PLENARY MEETING
OF THE SCIENTIFIC PANEL ON PLANT HEALTH, PLANT
PROTECTION PRODUCTS AND THEIR RESIDUES**

HELD IN BRUSSELS ON 30 JUNE 2004

(adopted by written procedure on 21 July 2004)

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PARTICIPANTS

Members of the PPR Panel

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

Apologies

Mrs E. PAPADOPOULOU-MOURKIDOU, Mr. M. MARONI.

EFSA

Mrs. M. DUNIER-THOMANN, Mr. C. LAURENT, J.O. MAGRANS and Mrs M. MESNAOUI.

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 two members.

2. ADOPTION OF THE AGENDA

The agenda was adopted without changes.

3. ADOPTION OF THE OPINION ON DINOCAPI

3.1 Question 1 on eye effect in dogs and relevance to humans

The rapporteur of the first question summarized the discussions in the Toxicology working group (WG) on 28th June to finalize the text. The oculotoxicity in the dog (tapetum lucidum) was extensively described. The uncertainties over the toxic mechanisms already raised during the previous working group meetings were discussed and agreed. The PPR Panel was of the opinion that the final draft report is well documented and that the wording of the text and the summary allows the reader to understand this difficult problem. The PPR Panel considered that there is not sufficient evidence to conclude that the eye effects of dinocap observed in dogs are specific to that species and, therefore, the effects cannot be regarded as irrelevant to humans.

3.2 Question 2 on dermal absorption

The rapporteur for question 2 explained the issue of dermal absorption and that the calculations for dermal absorption had been extensively discussed during the Toxicology WG. The Panel members agreed on the approach taken and on the appropriate value for dermal absorption, which can be derived by using the kinetic data from the mouse study and the *in vitro* comparative data with mouse and human skin. Correcting the excretion in mice after dermal exposure by the difference in dermal absorption between mouse and human *in vitro*, gives a range of values between 5% and 13%. The value calculated from the *in vitro* study with human skin was about 10% which is consistent with this range. The opinion on dinocap was adopted unanimously. The final draft opinion will be circulated for a last editorial check before publication on EFSA website.

4. PRESENTATION OF THE DRAFT 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 applications that do not lead to spray drift.

The rapporteur gave an overview of the draft opinion, prepared in Environment WG meetings with the help of two *ad hoc* experts. A request had been sent by EFSA to the 25 member states on dust deposition. To date 11 responses had been received.

The next discussion will take place at the next meeting of the WG Environment on 1st September.

The adoption of the opinion is foreseen at the PPR Panel plenary on 14-15th September.

5. PRESENTATION OF THE DRAFT 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 Env.WG meetings with the help of an *ad hoc* expert.

The next discussion will take place at the meeting of the Environment WG on 1st September. The adoption of this opinion is also foreseen at the PPR Panel plenary on 14-15th September.

6. PRESENTATION OF THE DRAFT OPINION ON ALACHLOR

6.1 Question 1 on nasal turbinate tumours in rats

The draft opinion on alachlor was presented by the rapporteur who emphasized the difficulty of the issues involved. Alachlor accumulates more in the nasal tissue of rats than in any others. Its metabolism is complex and its mode of action includes covalent binding to proteins.

From the extensive database available for genetic toxicology, it may be assumed that alachlor is unlikely to be considered as a mutagen, while some clastogenic effects have been observed in *in vitro* studies. However, this is not observed in *in vivo* studies.

The role of *in vitro* metabolic activation systems from different origins used in the different studies was also discussed: absent or weak activity having been found when using extracts from different tissues. While mutagenicity might occur at very high doses, the plausible mode of action seems to involve an epigenetic effect that would involve the production of metabolites that covalently binding to proteins, leading to increased cell proliferation and ultimately to neoplastic development.

6.2 Question 2 on the relevance of soil metabolites

The rapporteur and the members of the PPR Panel agreed that this issue is very complex (a large number of metabolites are generated) and related to the issues dealt with the first question. Additional clarification is needed from the Commission regarding how broadly the Toxicology WG should investigate this question. The final opinion could be completed for adoption on 28th October.

7. PRESENTATION OF THE DRAFT OPINIONS ON METHAMIDOPHOS

7.1 Toxicology

The rapporteur summarised the discussions of the Toxicology WG regarding the first draft. The scientific approach for the evaluation of the studies was welcomed and some rearrangements were agreed to improve the text in the next draft. The rapporteur pointed out some weaknesses in some of the provided studies and also some contradiction in the

background of the question which will be revised. The final opinion could be ready for adoption at the next plenary meeting after the Tox. WG on 13th September.

7.2 Ecotoxicology

The second draft opinion dealing with ecotoxicology (on birds and mammals) was presented by the rapporteur. It is envisaged that this will be a substantial document, which will serve as a reference for other substances. Field studies were detailed in two European countries and two *ad hoc* experts were contributing to the discussions, which will go on at the next Ecotoxicology WG to be held on 31st August. The final opinion could be ready for adoption at the plenary meeting on 28th October.

8. NEW QUESTIONS (DIMOXYSTROBIN,...) AND CALENDAR OF MEETINGS IN 2005

8.1 New questions from the Commission

A table was distributed detailing the expected questions by end of 2004/early 2005. The first new questions will be :

- on the variability factor for estimating acute consumer exposure through pesticide residues (under preparation in the Commission). It will be discussed and approved at the Plenary 14th-15th September and a new Working Group Residues will be created with some Panel members and *ad hoc* experts, when the volunteer rapporteur will be officially nominated.

The time constraint for adoption is 16 February 2005, as the Commission needs the opinion for the spring meeting of Codex/JMPR in March 2005. Some dates are already foreseen for the Residues WG meetings : 16th November and 13th December, to be confirmed.

- on the revision of Annexes II and III of the Directive 91/414/EEC, the sections on toxicology, ecotoxicology and physico-chemistry could be expected during autumn 2004. The “residue” section and the “fate and behavior” section probably by the end of 2004.

- on the three FOCUS Guidance Documents currently under preparation: the question on FOCUS degradation kinetics could in principle be expected around September 2004; FOCUS landscape and mitigation possibly in December 2004; FOCUS air by mid 2005.

8.2 New questions from EFSA in “self-tasking”

- The new question in ecotoxicology (on fish long term toxicity) on dimoxystrobin was accepted by the Panel and has the register number 81. A rapporteur was nominated, an *ad hoc* expert will be invited at the next Ecotoxicology WGs; the deadline for adoption of this opinion is 14th December 2004.

- Possible questions could be raised at the next WG Evaluation held in EFSA at mid-July.

8.3 Dates for the PPR Panel plenary and W G meetings in first half of 2005

The future plenary meetings are planned for 16th February, 6th April, 1st June, 6th July. The meetings should be held in principle in Parma, but other options will be discussed at the next Plenary meeting. A second day should be added if necessary.

Dates of the Working Group meetings : 15th February, 5th April, 31st May, 5th July. More dates will be selected later in the year depending of the new questions.

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

A. Hart, who is the project leader of the EU funded workshop “Improving the interface between RA-RM” in 2003, distributed this report. He introduced the 5 questions raised in the note distributed by EFSA to the members of all Panels.

In order to harmonize the comments by the PPR Panel on the final report, a template will be distributed after the Plenary meeting. The secretariat will collect the answers by 1st September and a discussion on the outcome will take place at the next plenary meeting of the Panel which will be held in Parma.

10 MISCELLANEOUS

- Update on the EFSA Document Management System

The external access to the EFSA Document Management System (DMS) by the Panel members should now be functioning, according to the information technology (IT) department. The Panel members who had not yet tested their access are requested to do so in order to give a feedback to the IT department of any problems.

- Mid-September meetings

The Toxicology WG meeting will be held at Milano University in the center of the city. Information was given on the local transportation from Linate and Malpensa airports to downtown. A shuttle will collect all the Panel members after the meeting in front of Milano University (departure 19h sharp) to transport them to Parma (about 2h30). The plenary meeting will start at 9h on 14th September and will continue the next day until mid-day. A shuttle will transport the Toxicology WG members back to airport, the Env. WG members will continue discussions and depart on 16th September mid-day.

- Three new members in the PPR Panel

The *Curriculum Vitae* of the three new Panel members were distributed. Their appointment was approved on 22nd June by the EFSA Management Board and these new members will be invited to join other Panel members at the next Plenary in Parma.

The next plenary meeting will be held on 14-15th September 2004, starting at 9h in Parma.