



**MINUTES OF THE 4<sup>TH</sup> PLENARY MEETING  
OF THE SCIENTIFIC PANEL ON PLANT HEALTH, PLANT  
PROTECTION PRODUCTS AND THEIR RESIDUES**

**HELD IN BRUSSELS ON 16 MARCH 2004**

**(Adopted by written procedure on 31 March 2004)**

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**AGENDA**

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**PARTICIPANTS**

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***Members of the PPR Panel***

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

***Apologies***

A. HART, H. KOEPP, K. SAVOLAINEN, A. SCHAEFFER.

***EFSA***

Mrs. M. DUNIER-THOMANN, S. HOFKENS, Mr. C. LAURENT, J.O. MAGRANS and Mrs M. MESNAOUL.

***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. Members were reminded of the need for commitment to attend the Working Groups (WG) and plenary meetings as a quorum of 2/3 of members (12) is required to hold a valid meeting, particularly when opinions have to be adopted.

## **2. ADOPTION OF THE AGENDA**

The agenda was adopted without changes.

## **3. DISCUSSION OF THE OPINION ON DAMINOZIDE**

The Toxicology Working Group had discussed the daminozide draft opinion prepared by the rapporteur on three occasions, the last one on 15<sup>th</sup> March. Unsymmetrical dimethylhydrazine (UDMH) is often found in daminozide as an impurity present at very small amounts, but also occurs in mammals as one of the metabolites of daminozide. UDMH has been shown to have weak genotoxic and/or mutagenic potential in some *in vitro* and *in vivo* studies. The members of the PPR Panel are concerned that confounding factors may have contributed to the patchy and inconsistent pattern of genotoxic and/or mutagenic potential of UDMH in the submitted studies. Since UDMH is converted to dimethylnitrosamine (NMDA) a known mutagen/carcinogen under oxidative conditions and/or the presence of light, the PPR Panel is of the opinion that the submitted studies should be reviewed according to the “status” of UDMH under testing (whether protected from oxidation or not). This is considered to be very important since it may clarify the intrinsic genotoxic/mutagenic properties of UDMH, that may be relevant to understanding the mechanisms of carcinogenicity, determining whether there is a threshold of toxicity and to advise on levels for workers exposure. The PPR Panel concluded that using the “protected” form, UDMH did not express genotoxic properties in the *in vitro* studies reviewed. However the situation is less clear for UDMH in the *in vivo* studies reviewed. Considering that quantitative and qualitative chemical characterization of the different batches of UDMH tested have not been performed or described, the PPR Panel considers that uncertainties remain regarding the biological relevance of the positive results described and the weight of evidence suggests that whilst the genotoxic potential of UDMH itself has not been clearly demonstrated the implications of the instability of the compound need careful consideration. This topic will further be discussed at the next meeting.

The WG Toxicology intends to finalize this opinion at its next meeting on 27th April to bring it forward for adoption at the next plenary meeting on 11th May.

## **4. PRESENTATION AND DISCUSSION OF THE OPINION ON DINOCAP**

### **4.1 Question 1 on eye effect in dogs and relevance to humans**

The Chair explained that an ophthalmologist had joined the Working Group as an *ad hoc* expert to the WG. The rapporteur who prepared the response to the first question

summarized the discussions to date. The oculotoxicity in the dog was extensively described with special attention to the “tapetum lucidum” effect. Some uncertainties remain as to whether the discoloration of the tapetum lucidum could be the only effect induced by dinocap, retinal atrophy having also been described. However, the available information does not allow concluding on primary or secondary retinopathy. Moreover because of the lack of an appropriate atapetal control group and data on the examination of both the tapetal and atapetal areas of the affected dog eyes, the significance of this is difficult to establish. The toxicological data reveal that the eye effects were observed not only in dogs but also in rabbits (cataract) and possibly in rats (retinopathy). In addition, some members were concerned that it was not known whether these effects are specific to dogs or whether they might occur in the retina or other eye tissues of other tapetal species. It was also noted that diagnosis of the effects was done about one year after the beginning of the study but there is no reported information on the evolution of the pathology over time. The mechanism of antifungal action of dinocap was explained; however from the available data, it is not possible to conclude that the effects observed in dogs are not relevant to human. The question of what kind of additional data would help to solve uncertainties was raised. Data on eyes effects from another tapetal species would certainly be useful and members were also of the opinion that mechanism of action should be explored further. The draft opinion will be revised and considered at the next Toxicology WG meeting to be held on 27th April.

#### **4.2 Question 2 on dermal absorption**

The rapporteur for question 2 explained the issue of dermal absorption. Additional documents that were requested from the notifier are now available and a draft opinion will be prepared and circulated for the next Toxicology WG.

The opinion on dinocap is expected to be completed for adoption by the end of June 2004.

### **5. CURRENT POSITION ON NEW QUESTIONS EXPECTED IN 2004, INCLUDING ALACHLOR AND METHAMIDOPHOS.**

#### **5.1 New questions from the Commission**

M. WALSH informed the PPR Panel of the possible timing of new questions originating from the first stage of the review programme:

- on alachlor (Spain is RMS): the two questions in toxicology have been agreed, one on the nasal turbinate tumours in the rat, the second on the toxicological significance of soil metabolites; the official response period of 6 months will start when all the related documents are sent to EFSA and forwarded to the rapporteur (in principle early April).
- on methamidophos (Italy is RMS): one question on toxicology and one on ecotoxicology are still under preparation (expected in principle by end of April)..

Concerning the current consultation on the revision of Annexes II and III of the Directive 91/414/EEC, the sections on toxicology, ecotoxicology and physico-chemistry are more advanced but still under preparation. The Commission has requested the comments of the

MS on the latest drafts by 20th March and the official request to the PPR Panel for an opinion could be expected by mid-2004.

On the residue section the comments of MS were requested by end of May by Commission, a discussion in a WG Evaluation will follow. The fate and behaviour section is less advanced and unlikely to be ready before the end of 2004.

Panel members were invited to send to the secretariat proposals for ecotoxicologists specialized in bees to be able to contact them as *ad hoc* experts when anticipated questions are raised in this specific area.

Three FOCUS Guidance Documents (GD) are currently under preparation in the Commission:

- on FOCUS degradation kinetics, it should in principle be finalized by September 2004;
  - on FOCUS landscape and mitigation possibly in autumn 2004;
  - on FOCUS air: a meeting of the Commission WG is foreseen on 22<sup>th</sup> March, another meeting is expected to finalize the document in September.
- They will be send to EFSA for opinion, as it was done with SCP in the past.

## **5.2 New questions from EFSA in “self-tasking”**

- The Chair introduced J.O. MAGRANS, a new member of EFSA staff from the Risk Assessment of the Peer Review programme (PRAPeR). A scientist from Spain, his expertise is in the fate and behaviour of plant protection products, he will also occasionally provide support to the PPR Panel.

The PRAPeR sector has identified the need for advice from the PPR Panel relating to the Peer Review of the second list (of 52 active substances). This is a general question rather than related to a particular active substance: the question deals with the relevance of applying the “FOCUS Surface water” scenarios to calculate the predicted environmental concentrations in surface water to be used for the risk assessment of aquatic organisms. J.O. MAGRANS explained the context of this request and a draft terms of reference and background was circulated. The principle of this question was agreed and the first discussion will take place at the next meeting of the WG Environment on 1st April.

A second request on FOCUS ground water models is also in preparation and will be presented that day.

- A possible request from another EFSA Panel is under discussion internally. The Scientific Committee should be involved in the guidance on how to manage these self-tasking bridging questions and their prioritization versus other questions.

- Five possible toxicology topics for consideration were suggested by K. MACHERA. It was agreed that a general discussion to identify and prioritize such self-tasking questions should take place in a future plenary meeting.

## **5.3 Dates for the PPR Panel plenary and Working Group meetings in 2004:**

Future plenary meetings in 2004 are planned for 11<sup>th</sup> May, 30<sup>th</sup> June, 14<sup>th</sup> September\*, 28<sup>th</sup> October and 14<sup>th</sup> December.

\*: the meeting will be held in Parma to assess the logistics, travel times and the organization required to meet in Parma.

***Dates of the Toxicology Working Group meetings :***

27<sup>th</sup> April, 10<sup>th</sup> May p.m.only, 29<sup>th</sup> June, 13<sup>th</sup> September\*, 27<sup>th</sup> October, 16<sup>th</sup> November, 13<sup>th</sup> December.

\*: the meeting will be held in Milano, M. MARONI made a proposal to host the WG in Milano University in the center of the city, the local transportation from Linate and Malpensa airports are easy. Buses will collect the WG members after the meeting, together with the other members of the Panel arriving during the day, to transport them to Parma (2h) for an overnight stay and the plenary the next day. Buses will transport the members back to airports after the meeting which consequently will finish early. The WG members were asked to send by end of March their request for reservation of hotel in Milano during the week-end 11-12 September to M. MARONI (copy to the secretariat). They were also asked to check the time table for travel from their hometown and inform the secretariat of their wish for the pre-paid ticket.

***Dates of the Environment Working Group meetings:***

The Chair proposed to reserve provisional dates for the Environment WG: 1<sup>st</sup> April, 29<sup>th</sup> April, 10<sup>th</sup> May (to be confirmed), 2<sup>nd</sup> June, 29<sup>th</sup> June, 15<sup>th</sup> September\*.

\*: in Parma.

More dates will be selected later in the year depending of the new questions; the Ecotoxicology WG could be reactivated when the question in ecotoxicology on methamidophos will be official.

## **6. ANY OTHER BUSINESS**

**- Call for recruitment of new members in the PPR Panel**

The EFSA 2004 call closed on 15th March. Three new members will be recruited to the PPR Panel in those areas of expertise currently with few members and according to the anticipated future requests for advice in the Management Plan (questions from the Commission, self-tasking, etc)

**- Change in the PPR Panel representation in the GENTOX Working Group**

The WG of the Scientific Committee on a harmonised approach for genotoxic and carcinogenic substances (GENTOX) has met several times. Initially K. SAVOLAINEN represented the PPR Panel but at his request will be replaced by D. MCGREGOR from the next meeting 26 April 2004. Feedback on progress will be given to the Panel in the next plenary meeting.

**- Information on the EFSA Document Management System**

Access to the new EFSA Document Management System (DMS) was demonstrated by the informatics technology (IT) department (E. HINSON). Members will be informed by e-mail when the system goes live, ID and passwords were attributed.

Toxicology members were trained in the last two WGs, the same training will be offered to the 9 other members of the Panel at the WG Environment on 1<sup>st</sup> April.

As requested in a previous meeting, a link was created to the DG SANCO web site under the item "Legislation" to access directly those directives and regulations on pesticides relating to Directive 91/414/EEC.

**- EFSA code of conduct on declaration of interest**

The document endorsed by the Management Board at its meeting of the 10<sup>th</sup> March was distributed; the paper is intended to give guidance on direct and indirect interests and the necessity to declare them in order to avoid potential conflicts of interest. The renewal of the annual declarations done on 22<sup>nd</sup> May 2003 will be requested at the next plenary meeting.

The next plenary meeting will be held on 11<sup>th</sup> May 2004, starting at 9h.