



**MINUTES OF THE 15<sup>TH</sup> PLENARY MEETING  
OF THE SCIENTIFIC PANEL ON PLANT HEALTH, PLANT PROTECTION  
PRODUCTS AND THEIR RESIDUES**

**HELD IN PARMA ON 14-15 DECEMBER 2005**

(Adopted by written procedure on 10 January 2006)

**Agenda**

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## **PARTICIPANTS**

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### ***Members of the PPR Panel***

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

### ***EFSA***

Mrs. M. DUNIER-THOMANN, Mr. B. BERGER, Mrs. E. CEGLARSKA, Ms. C. FUELL, Mrs. A. DE BLOCK and Ms. G. BOSCHETTO. Mr. H. BRUNO from PRAPeR joined the meeting on 15 Dec 2005.

### ***European Commission***

Mrs. F. ARENA (DG SANCO, D3 Chemicals, contaminants and pesticides).

## **1. WELCOME, APOLOGIES FOR ABSENCE**

The chairman, Mr. A. HARDY, welcomed the participants. Apologies had been received from, Mr. R. BLACK, W. STEURBAUT, and Mr. M. WALSH (Interface Unit, DG SANCO D6).

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

The agenda was adopted with only slight changes with regard to the order of items. No new declarations of interests/conflicts of interest were made. The chairman welcomed Mrs. F. ARENA from DG SANCO who briefly introduced herself.

The chairman emphasised that working documents on draft opinions are confidential and have to be treated accordingly since they might change considerably during the elaboration of the opinion. Also the discussions in the Working Groups are confidential. Further, he reminded the participants that the final Opinions reflect a consensus view on one issue and have to be communicated accordingly to the public.

## **3. ADOPTION OF THE OPINION ON THE ASSESSMENT OF THE ACUTE AND CHRONIC RISK TO AQUATIC ORGANISMS**

The rapporteur of the draft opinion, on the assessment of the acute and chronic risk to aquatic organisms, with regard to lowering the assessment factor if additional species are

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tested, (a self-tasking question at the request of the PRAPeR sector of EFSA), presented the outcome of the final discussions during the Ecotoxicology WG meeting on 14 December 2005 and explained the changes made since the last version of the draft opinion. These changes are basically of structural nature in order to make the opinion more reader-friendly.

The rapporteur explained that the current risk assessment shows a difference in conservatism if a higher number of species is tested and that the level of protection between different species is different as well as between different compounds. He then outlined possible solutions comprising various statistical approaches to deal with these problems. The opinion will offer an overview of the pros and cons of the different methods as well as the various options and their implications. However it is up to the risk manager to choose the level of protection.

The Panel members made further comments and amendments, which were included in the opinion. The opinion was formally adopted by the PPR Panel. The rapporteur will do some final editorial improvements on the text and clarification of some terms that are differently used within toxicology and ecotoxicology before circulation and final approval by 12 January 2006. The opinion will then be published on the EFSA web in January 2006.

#### **4. DISCUSSION ON THE DRAFT OPINION ON THE DEFAULT Q10 VALUE USED TO DESCRIBE TEMPERATURE EFFECT ON TRANSFORMATION RATE OF PESTICIDE IN SOIL**

The rapporteur described the present status of the draft opinion which adoption was postponed to the next Plenary meeting on 8th February. Questions 1 and 2 have been worked-out in detail and finalised but question 3 still needs some refinement in relation to statistical analysis. The Panel appreciated the work done so far, several minor comments were made with regards to statistical analysis. It was recommended to clearly indicate levels for calculations of significance and confidence.

The Fate WG will finalise the opinion on 7<sup>th</sup> February before the plenary meeting.

#### **5. DISCUSSION ON THE DRAFT OPINION ON CYPRODINIL: ASSESSMENT OF A MICROCOSM STUDY**

The rapporteurs gave an update on the development of this opinion since the last Ecotoxicology and Fate WG meeting, which took place 13-14 December 2005 in Parma.

The rapporteur explained that the remaining open questions have been answered. Now some final adjustments are left. With regard to question 1 it can be concluded that the relevant study and results can be used for environmental conditions in Europe. Concerning question 2, there are three methods that give - within one order of magnitude - an answer for the risk assessment. A final commenting round will take place until 20

December 2005, then the rapporteur will make the final version to be adopted during the 16<sup>th</sup> PPR Plenary in February 2006. A last meeting on the final draft will take place on the 07<sup>th</sup> February 2006 prior to the Plenary.

## **6. ADOPTION OF THE OPINION ON THE FOCUS DEGRADATION KINETICS GUIDANCE DOCUMENT**

The draft opinion finalised in a Fate WG on 13/14<sup>th</sup> December was presented by the rapporteur, the Panel supports the Guidance Document and made some recommendations. After discussion and having regard to the increasing importance of uncertainties in risk assessment, the Panel decided to more explicitly address issues of statistical uncertainties, to introduce some minor modifications and to add a specific remark on that to the draft opinion. This should encourage the addressing of uncertainties in any revisions of the Guidance Document.

The opinion was formally adopted by the PPR Panel with this modification. The EFSA Secretariat will circulate the adopted version, asking the PPR Panel members for final editorial comments and agreement by 06 January 2006. The opinion will then be published on the EFSA web in January 2006.

## **7. PRESENTATION AND ACCEPTATION OF NEW QUESTIONS**

### **• Question from the Commission on AOEL Guidance Document**

The official submission from the Commission to the PPR Panel of a question on the acceptable operator exposure levels (AOEL) Guidance Document (GD) was presented. The PPR Panel officially accepted the question and the Panel consequently discussed the issue of “declaration of interest”.

As the very short deadline requested is unlikely to be met, after negotiation with the Commission (F. ARENA), the adoption of the opinion is envisaged more likely for May 2006. A rapporteur was agreed.

F. ARENA explained the history of the GD, started in 1995, revised in 2005 after consultation of the SCP, the present document is the Revision 9 of the GD. The comments of Member States and ECPA were delivered to the Panel.

The issue of the use of human data was shortly discussed and F. ARENA clarified the position of the Commission, a document (from June 2003) will be made available on the extranet by the secretariat.

The next discussion in the Toxicology Working Group will take place on 15/16 December 2005.

### **• Three questions from the Commission on the revision of Annexes II and III to Directive 91/414**

A request for opinions on the revision of the Annexes II and III of the Directive 91/414 in the area of residues, physico-chemistry and analytical methods has been

submitted by the Commission. F. ARENA presented the context of these requests, and the PPR Panel officially adopted the 3 requests after the too short deadline was agreed by the Commission to be extended to May 2006. A first meeting will take place on 19 January 2006, colleagues from the PRAPeR team will joint the meeting.

## **8. FEEDBACK ON OPINIONS UNDER PREPARATION**

### **• NOEC mammals:**

The 13th PPR Panel Plenary meeting on 15/16 September 2005 officially launched this question on the assessment of the long term risk to mammals, a self-tasking question at the request of the PRAPeR sector of EFSA.

Many risk assessments do not carry out a specific risk assessment for mammals. Instead, the lowest available toxicity value is taken from human risk assessment, however, it is difficult to choose the right endpoint. In principle a method to assess the risk for mammals is available from a workshop that took place in York/UK, it has to be discussed if the outcome of this workshop is useful, i.e. if the phase specific approach is suitable or if a different approach is needed.

Two questions were addressed to the Panel:

Question 1. 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.

Question 2. 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.

One rapporteur reported on the first meeting of the Working Group with help of an *ad hoc* expert on 10<sup>th</sup> November 2005 and the ongoing work. The Panel then engaged in a discussion, in particular the possibilities and difficulties to extrapolate findings between species and how to identify which are the significant effects. It was recalled that the legislation prohibits unacceptable adverse effects, but does not define them clearly. The Panel will therefore need to address this aspect in the opinion. The next meeting will take place on 17-18<sup>th</sup> January 2006.

### **• Dichlorvos:**

The rapporteur presented the first draft opinion, following a first discussion at the Tox. WG on 24/25th November. The Panel then discussed how to treat all existing studies/information forming the basis of the draft opinion. The Tox. WG will continue the preparation of this opinion on 16<sup>th</sup> December.

### **• Summary of adopted opinions in environmental and toxicology:**

On 18<sup>th</sup> November 2005 the chairman sent a letter to G. Podger with a self-tasking request from the PPR Panel, to summarize the outcome of the adopted opinions since the beginning of this Panel in 2003.

For the summary of the environmental opinions, the Panel decided to have a first discussion on 7<sup>th</sup> February (at the end of the two WG Fate and WG Ecotoxicology). For the summary of the toxicology opinions, a first draft addressing general conclusions of a wider interest to be extracted from these 5 adopted opinions, has been circulated after the discussion at the Toxicology Working Group on 25<sup>th</sup> November. This WG will continue to prepare the draft opinion on 15/16<sup>th</sup> December.

## **9. FEEDBACK FROM THE SCIENTIFIC COMMITTEE, WG EXPOSURE, GENTOX AND RA-RM**

The chairman postponed this item to the next Plenary meeting due to lack of time. Mr. D McGregor will attend the first meeting of the Benchmark Dose WG of the Scientific Committee to be held on 16th December, in Amsterdam.

## **10. MISCELLANEOUS**

### **Call for renewal of Panels and creation of the new Panel on Plant Health**

The call for expression of interest in membership of the Scientific Committee and the EFSA Panels, including the new Panel on Plant Health (PLH Panel) has been published in the Official Journal on 22 November 2005, as well as put on the EFSA web. As in the past, an online application is recommended; the closing date will be 07 January 2006. All Panel members wishing to participate to the next PPR Panel will have to reapply.

The 16<sup>th</sup> PPR Panel Plenary meeting will take place on **08 February 2006 in Parma.**