



MINUTES OF THE 12TH PLENARY MEETING OF THE SCIENTIFIC PANEL ON PLANT HEALTH, PLANT PROTECTION PRODUCTS AND THEIR RESIDUES HELD IN PARMA ON 6 JULY 2005

(Adopted by written procedure on 08 August 2005)

AGENDA

1.	Welcome, apologies for absence
2.	Adoption of the agenda
3.	Adoption of the opinion on pirimicarb
4.	Discussion of the draft opinion on the assessment of the acute and chronic risk to aquatic organisms
5.	Discussion of the draft opinion on the default Q10 value
6.	Discussion and adoption of new questions in ecotoxicology <ul style="list-style-type: none">• Cyprodinil: assessment of microcosm study• Use of mammal NOECs in ecotox Risk Assessment
7.	Discussion on the prioritisation of the future self-tasking questions
8.	Presentation and adoption of a new question on the FOCUS degradation kinetics Guidance Document
9.	Information on the delivery of conclusions in the Peer review of the risk assessment of the second list of active substances by the PRAPeR sector of EFSA: 1-MCP, tolclofos-methyl and triticonazole
10.	Feedback from the Scientific Committee 21/22 nd June, WGs Exposure, Gentox and RA-RM
11.	Miscellaneous <ul style="list-style-type: none">• On going revision of Council Directive 91/414/EEC of 15 July 1991• Info from DG RTD• Article 36 of the EFSA legislation

PARTICIPANTS

Members of the PPR Panel

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

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European Commission

Apologies from Mr. M. WALSH (Interface Unit, DG SANCO D6)

1. WELCOME, APOLOGIES FOR ABSENCE

The Chairman, Mr. A. Hardy, welcomed the participants; apologies had been received from M. Walsh.

2. ADOPTION OF THE AGENDA

The agenda was adopted without changes. Mr. McGregor declared a conflict of interests for pirimicarb.

3. ADOPTION ON THE OPINION ON PIRIMICARB

The two rapporteurs presented the outcome of the detailed discussion during the Ecotoxicology WG on 05 July 2005 on the pirimicarb opinion (a self-tasking question at the request of the PRAPeR sector of EFSA). The PPR was requested to give an opinion on the 'time quotient approach' according to OECD (1996) and the assessment of the acute risk to birds from the use of pirimicarb. The Panel members made further comments and amendments, which were included in the opinion. The opinion was formally adopted by the PPR Panel. The rapporteurs will do some final improvements on the text and the EFSA secretariat will do the editorial check (incl. references, acknowledgements etc.). The opinion will then be circulated by the secretariat asking the PPR Panel members to confirm the adoption by 28 July 2005. The opinion will then be published on the EFSA web. Douglas McGregor had expressed a conflict of interests and withdrew from these discussions.

4. DISCUSSION OF THE DRAFT 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 tested, a self-tasking question at the request of the PRAPeR sector of EFSA) presented the outcome of the discussion during the Ecotoxicology WG meeting on 05 July 2005 and the state of the opinion, including the comprehensive statistical work done by four *ad hoc* experts (statisticians). The rapporteur explained the current inconsistency with regard to the level of protection and application of safety factors and outlined a possible solution how to tackle

these problems. The question will be discussed again during the next Ecotox WG to be held on 06 September in Brussels. The adoption of the opinion is foreseen during the 13th PPR plenary meeting on 15-16 September 2005.

5. DISCUSSION OF THE DRAFT OPINION ON THE DEFAULT Q10 VALUE

The draft opinion on the default Q10 value used to describe the temperature effect on transformation rates of pesticides in soil (from the PRAPeR sector of EFSA) was presented by the rapporteur. An *ad hoc* expert was invited to support the WG. For elaboration of the question a data base was produced based on review of open literature and Draft Assessment Reports of 52 active substances. In total fifty-five papers have been reviewed and included. The next Fate WG will take place on 7-8 September in Parma.

6. DISCUSSION AND ADOPTION OF NEW QUESTIONS IN ECOTOXICOLOGY

- **Cyprodinil: assessment of microcosm study**

The two rapporteurs introduced these new questions (one related to exposure, one related to ecotoxicological endpoints) on the assessment of a microcosm study for the risk assessment of cyprodinil. The chairman will agree in an official letter to the wording of the request of PRAPeR sector of EFSA after the plenary meeting., Three *ad hoc* experts will be invited to join the WGs. The PPR Panel is aiming for an adoption of the opinion by mid-December 2005.

- **Use of mammalian NOECs in ecotoxicological risk assessment**

The two rapporteurs introduced these new questions on the assessment of the long term risk to mammals. The PPR Panel considered one part of the questions as being clearly formulated. However, the second part of the question seems to be too broad to be answered in the given time frame of six months. The PRAPeR sector will discuss the wording again with the experts and a new wording will be confirmed during the WG Ecotox Meeting on 06 September 2005. During that meeting the participation of further *ad hoc* experts will be considered as appropriate and they will be invited to the future WGs. The question will be launched at the September plenary and an adoption of the opinion could take place in mid-February 2006.

7. DISCUSSION ON THE PRIORITISATION OF FUTURE SELF-TASKING QUESTIONS

The PPR Panel briefly discussed the ranking list of self-tasking issues, prepared according the discussions during the last plenary meeting. The feasibility of some opinions (i.e. summarizing/reviewing the environmental and toxicological opinions adopted since the creation of EFSA), and the possible timing was discussed.

A more detailed discussion will take place at the next plenary meeting in September 2005. Two PPR panel members will each write a page on what could be done with regard to the

top four issues on the list. However, these self-tasking issues will be treated with lower priority than the requests from Commission and from the PRApEr, because of the legal framework constraining time (one year period for issuing the EFSA conclusions according to the legislation). The finalisation, however, has to take place before the end of the PPR Panels' three years mandate (i.e. by May 2006).

New questions expected

The Scientific Coordinator of the PPR Panel informed the members of newly expected questions.

- In toxicology: the AOEL guidance document should arrive in EFSA by early October (from Commission) and a new question from the last EPCO Toxicology Expert Meetings in the peer review process (self-tasking from PRApEr) should arrive soon.
- In fate: few Guidance Documents are expected by end of the year.
- Questions on the current amendment of the different areas of the Annex II and III of Directive 91/414/EEC in physico-chemistry, analytical methods and residues are also expected to be submitted to the Panel by October 2005.

8. PRESENTATION AND ADOPTION OF A NEW QUESTION ON THE FOCUS DEGRADATION KINETICS GUIDANCE DOCUMENT

The Guidance Document is a large (475 pages) technical document agreed by the MS. The request in principle consists of two questions: (a) whether the methodology and approaches presented in the GD are in line with the state of art in the field of environmental chemistry and (b) to what extent the GD can be applied with respect to the RA of pesticides. Involvement of new *ad hoc* experts was considered necessary in relation to degradation kinetics in ecosystems.

The question was officially accepted by EFSA but the deadline of 28 July 2005 was felt unacceptable due to the extent of the document and the work to be done. Also, the Panel pointed out that the existing work programme cannot be set aside. It was therefore recommended to deliver the opinion within the standard timeframe, i.e. 6 months and prepare it for adoption on 09 November 2005.

9. INFORMATION ON THE DELIVERY OF CONCLUSIONS IN THE PEER REVIEW OF THE RISK ASSESSMENT OF THE SECOND LIST OF ACTIVE SUBSTANCES BY THE PRApEr SECTOR OF EFSA

The secretariat circulated, for information, three new conclusions emitted by the PRApEr sector of EFSA on the Peer Review of the risk assessment of active substances of the second list of active substances: 1-MCP, tolclofos-methyl and triticonazole, finalised respectively on 2nd May and 22th June.

The comments of the PPR Panel members wishing to contribute to these conclusions should be sent directly to Mr. H. Bruno, the Scientific Coordinator of the PRApEr.

10. FEEDBACK FROM THE SCIENTIFIC COMMITTEE 21-22TH JUNE, WG EXPOSURE AND GENTOX AND RA-RM

The chairman gave a feedback on the last meeting of the Scientific Committee and WGs. A meeting of an ad-hoc WG on the “Interface between risk assessment and risk management” (follow up of the Workshop in the Netherlands in September 2003) took place on June 20, another one should finalise the opinion in September 2005.

- Mr. A. Hart gave feedback on the state of the work on the guideline document of the Working Group Exposure.
- The GENTOX WG (Mr. D. McGregor) will discuss the public comments received on the draft opinion on a “Harmonised Approach for Risk Assessment of Compounds that are both Genotoxic and Carcinogenic” at the next WG on 13 July 2005 after the feedback from Panels and from the public consultation of April 2005. In view of the unavailability of the PPR panel designated members of the WG, Mrs. Vleminckx kindly consented to represent the views of the PPR.

11. MISCELLANEOUS

The chairman gave a feedback on the EFSA’s inauguration day on 21 June in Parma, with the participation of Mr. Berlusconi and Mr. Barroso (president EU Commission) and about 350 invited guests, including the SC members.

1. Ongoing revision of Council Directive 91/414/EEC of 15 July 1991

The DG SANCO’s proposal (SANCO/10159/2005) was commented on by the member states (MS) and EFSA in May. A new draft will be presented at the next Standing Committee of DG SANCO mid July 2005, a vote of MS will possibly take place at the September Standing Committee.

2. Info from DG RTD on the 7th Framework Programme of R&D

The secretariat informed that Mr. R. Hardwick, from DG RTD, in charge of pesticides and plant health area will retire this summer. The secretariat will keep close contact with the new desk officer to be kept informed on the development of DG RTD programmes.

Documents had been circulated to the PPR Panel members to inform them on the preparation of the forthcoming 7th Framework Programme of the EU (2007-2011), including the address of an open consultation available on the DG RTD website.

3. Article 36 (para.3) of the EFSA Regulation 178/2002

A request to MS to nominate competent national organizations operating in the field of EFSA’s mission in order to build a network of expertise should be send in August 2005 by EFSA together with a questionnaire.

The Chairman referred to his note to the last SC concerning the problems for experts of holding the plenary meetings in Parma. A reflection is ongoing in EFSA, and an answer will be given by September.

Mr. M. Maroni offered to host the next Toxicology WGs in the University of Milano so that a direct access from the airport Malpensa could save time for transportation.

The next plenary meeting will be held on **15 (p.m.) and 16 September (a.m.) 2005** in Parma, with a one and half day Working Group meeting (Ecotox + Fate WG) on 14 and 15 a.m. September.

A table of the next meetings in 2005 and meetings in early 2006 is attached.