



**MINUTES OF THE 14TH PLENARY MEETING
OF THE SCIENTIFIC PANEL ON PLANT HEALTH, PLANT PROTECTION
PRODUCTS AND THEIR RESIDUES**

HELD IN PARMA ON 09 NOVEMBER 2005

(Adopted by written procedure on 01 December 2005)

Agenda

#	Items
1.	Welcome, apologies for absence, declaration of interests
2.	Adoption of the agenda
3.	Adoption of the opinion on the assessment of the acute and chronic risk to aquatic organisms
4.	Update on the opinion on Q 10 value used to describe temperature effect on transformation rate of pesticide in soil
5.	Update on the opinion on the FOCUS degradation kinetics Guidance Document
6.	Update on the draft opinion on cyprodinil: assessment of microcosm study
7.	<p>Presentation and acceptance of new questions:</p> <ul style="list-style-type: none">• Question from PRAPeR on residues - consumer exposure (MRL)• Self tasking: 2 summary-opinions on the adopted opinions in toxicology and environment (short presentation of possible structure)• New question in toxicology on dichlorvos• Update on the question from the Commission on FOCUS landscape and mitigation Guidance Document
8.	Feedback from the Scientific Committee, WGs Exposure, Gentox and RA-RM
9.	Info from DG RTD on the 6 th and the 7 th Framework Programme
10.	<p>Miscellaneous:</p> <ul style="list-style-type: none">• Timing of the call for renewal of Panels and creation of the new Panel on Plant Health• Project of new PPR Panel's page on EFSA's website

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, Mrs. K. MACHERA, Mr. M. MARONI, Mr. D. McGREGOR, Mr. O. MEYER, Mrs. E. MOURKIDOU-PAPADOPOLOU, Mr. E. PETZINGER, Mr. K. SAVOLAINEN, Mr. J. STENSTRÖM, Mr. W. STEURBAUT, and Ms. D. TSIPI-STEFANITSI.

EFSA

Mrs. M. DUNIER-THOMANN, Ms. C. FUELL, Mr. B. BERGER, Mrs. A. DE BLOCK and Ms. M. MESNAOUI. Mrs. M. NORDIN-ANDERSSON, Mrs. M. TIRAMANI, and Mrs. F. ISTACE from the PRAPeR Team joined the meeting for the discussion on dichlorvos.

European Commission

Mr. M. WALSH (Interface Unit, DG SANCO D6) and Mr. P. VENTURI (DG RTD E3).

1. WELCOME, APOLOGIES FOR ABSENCE

The chairman, Mr. A. HARDY, welcomed the participants. Apologies had been received from Mr. A. MORETTO, Mrs. C. VLEMINCKX and E. CEGLARSKA.

2. ADOPTION OF THE AGENDA

The agenda was adopted without changes. The chairman warmly welcomed Mr. Bernhard BERGER, a new colleague within the PPR Secretariat, who briefly introduced himself. Several PPR Panel Members declared an interest for the new question in toxicology on dichlorvos.

3. DISCUSSION 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 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 08 November 2005 and the state of the opinion. It had been planned to adopt the opinion during this 14th Plenary meeting but despite considerable work the opinion was not sufficiently complete to adopt. This opinion is likely to have a large impact on the risk assessment of the second list of active substances done by Member States and coordinated by PRAPeR in the future.

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 rapporteur further explained the new structure of the opinion which was discussed during the WG Ecotoxicology on 08 November 2005, as outlined in a new draft circulated for the Plenary. One particular reason for restructuring the opinion is to place two "simple methods" more upfront to make it easier for the reader to understand the problem and its solution. The rapporteur also guided the Panel members through the summary of the opinion.

During the WG Ecotoxicology on 08 November 2005 working tasks had been clearly assigned to the members and their respective contributions are required by the rapporteur by 18 November 2005. The draft opinion will be discussed again during the next Ecotoxicology and Fate WG to be held on 24 November 2005 in Roskilde/Denmark. The adoption of the opinion is now foreseen during the 15th PPR Plenary meeting on 15th December 2005. This timeline for action was strongly emphasised by the chairman.

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

The rapporteur presented the draft opinion, already updated with comments made during the discussion by the Working Group Fate on 08 November 2005 as well as some updated statistical calculations. Regarding Question 1 on the Q10 opinion, the quality criteria for the inclusion of data in the Panel's database and the preliminary conclusion were presented and briefly discussed. Regarding Question 2, the rapporteur informed the Panel that the WG had decided to focus on the influence of chemical structure. The Panel discussed the most suitable statistical approaches to determine whether particular chemical families (e.g. phenylureas) have significantly different activation energies. Regarding Question 3, the rapporteur reported the preliminary results of temperature dependency on activation energy. The discussion focused on the interpretation of the statistical calculations, the best way to present and treat the data, as well as on further possible methods and approaches for statistical analysis.

The WG will continue to discuss these issues in its next meeting on 25 November 2005 in Roskilde/Denmark and the rapporteur expressed confidence to meet the target December Plenary meeting to adopt the opinion.

5. DISCUSSION ON THE QUESTION ON THE FOCUS DEGRADATION KINETICS GUIDANCE DOCUMENT

The rapporteur presented the state of the art of the draft opinion and reported from the discussion of the WG on 08 November 2005 in which several *ad hoc* experts were involved. The discussion focused on LOD/LOQ, the way the χ^2 test has been applied and presented, and the treatment of outliers. A revised version will be available for the next WG meeting on 25 November 2005 in Roskilde/Denmark and adoption is still scheduled for the mid-December Plenary meeting.

The chairman emphasised that this opinion is different from other opinions produced by the Panel, taking the form of a peer review and therefore is shorter than most Panel opinions. It will probably not lead to immediate modifications of the document (on which the Commission has already received extensive comments from Member States), but rather highlight issues to be considered and revised in the future. As more planned Guidance Documents will be sent to the Panel for an opinion, this opinion is likely to be the precursor for how they will be treated by the Panel. The adoption of the opinion is foreseen to be at the next Plenary meeting mid-December.

6. DISCUSSION ON THE DRAFT OPINION ON CYPRODINIL: ASSESSMENT OF A MICROCOOSM STUDY

The rapporteurs gave an update on the development of this opinion since the last Ecotoxicology and Fate WG meeting, which took place 03 October 2005 in Brussels. A revised version of the opinion has been submitted to the Panel members. The part dealing with exposure will be finalised by early December since most of the outstanding issues have been dealt with. The part dealing with ecotoxicology has been extended to include various comments made during the last meeting. However, this part needs some further discussion during the next Ecotoxicology and Fate WG meeting to be held on 24 November 2005 in Roskilde/Denmark. The rapporteurs will prepare a new revision of the opinion before the next WG. The PPR Panel is aiming for an adoption of the opinion during its Plenary meeting on 14-15 December 2005.

7. PRESENTATION AND ACCEPTATION OF NEW QUESTIONS

- Question from PRAPeR on residues - consumer exposure (MRL)**

The official submission from the EFSA PRAPeR unit to the PPR Panel of a question on the most appropriate diet(s) to be used for determining the potential chronic and acute exposures of consumers of the EU to residues resulting from the proposed temporary MRLs, as announced at the last Plenary, is still expected. Several PPR Panel members expressed their interest to contribute to a new Residue working group when the question has been clarified and submitted. An *ad hoc* expert should also join this WG. A first meeting could possibly take place

on 11 January 2006 if the question can be officially adopted during the Plenary meeting in December 2005.

- **Update on question from the Commission on FOCUS landscape and mitigation Guidance Document**

The official submission from the Commission of this question is still pending, following the Panel's request for clarification. It will probably be available at the next Plenary meeting mid-December 2005.

- **Self-tasking on summary-opinions for adopted opinions in toxicology and environment**

During its 12th Plenary meeting the PPR Panel discussed the possibility to elaborate in the two fields of environment and toxicology a summary of the important conclusions raised in the opinions adopted since the creation of EFSA. The chairman repeated that the Panel members considered these summaries as being very valuable, and that a positive feedback on this idea has also been received from the members of the Scientific Committee and some Member States. The representative of the Commission also strongly supported this idea. Most of the work could be done by the rapporteurs electronically after initial discussion meetings to agree content, approach and framework. The structure doesn't necessarily have to be the same for both opinions, but the opinions should have the same philosophy. After the Plenary meeting the chairman will send a note to Geoffrey Podger outlining what the PPR Panel intends to do. Rapporteurs have been identified for both, the environment- and the toxicology-opinion and should prepare soon a structure for the first discussion.

These two opinions should be finalised before the PPR Panel comes to the end of its 3-year term by May 2006 because they are directly related to the current Panel. The starting discussion for the summary opinion with regard to the toxicological issues will take place during the Toxicology WG meeting on 24/25 November 2005 in Parma; the one for the summary opinion with regard to the environmental issues will take place either during the Ecotoxicology and Fate WG meeting on 24 November 2005 in Roskilde/Denmark or in December 2005. Ideas and views should be exchanged briefly during the Plenary meeting in December.

- **New question in toxicology on dichlorvos**

A member of the PRAPeR team introduced this new question regarding the carcinogenic and mutagenic properties of dichlorvos. The PRAPeR team will provide a revised wording of the terms of reference taking into account the comments made by the Panel members. A rapporteur has been identified. The work will start during the WG Toxicology 24/25 November 2005 in Parma.

As mentioned already under agenda item 2, several experts declared an interest with regard to dichlorvos since they have been professionally involved in this topic before. They will have to clarify how closely they have been involved in a decision

making process with regard to dichlorvos when filling the "declaration of interest" form.

- **New questions from the Commission**

M. Walsh informed the Panel that the following new questions will be sent soon by DG SANCO to the PPR Panel:

- on the Acceptable Operator Exposure Levels (AOELs) guidance document.
- on the amendment of the Annexes II and III of the Directive 91/414 in the area of residues, physico-chemistry and analytical methods. The PRAPeR team of EFSA should be the main unit involved for the last two subjects with their in house experts in charge of the risk assessment of the second list of active substances. Some Panel members offered to assist them.

8. FEEDBACK FROM THE SCIENTIFIC COMMITTEE, WG EXPOSURE, GENTOX AND RA-RM

- The chairman gave feedback on the ongoing work within the Scientific Committee and its WGs. He informed about the joint meeting between the GMO Panel and the PPR Panel, DG SANCO and DG ENV on 19 October 2005 in Brussels, where the participants identified the areas of common interest and the boundaries in the risk assessment under the two related Directives (e.g. GM crop/herbicide programme). The minutes of this meeting will be sent to the PPR Panel members for information.
- The chairman also informed that the draft of the guidance document on the Interface between Risk Assessment and Risk Management is still under consideration in the WG. However, there are no new developments to report.
- A meeting will take place on 7-8th December in Brussels to draw together the chairs of the Scientific Committees of Community bodies involved in risk assessment (to include EFSA committees and the Scientific Coordinators, with the non-food Committees from DG SANCO, EMEA, EMPL, and EEA), chaired by R. Madelin, the Director General. This first meeting aims to stimulate closer collaboration and harmonisation of the community approach to risk assessment.
- Mr. A. HART gave an overview on the main issues the WG Exposure discussed during the meeting on 7-8 November 2005. These concern the human exposure to epoxidised soybean oil (ESBO, a softening agent/plasticiser) and an assessment on ochratoxin A (OTA). The draft on uncertainty of exposure assessment is nearly ready, and will be send to the Scientific Panels for a first feedback approximately mid-November 2005. One member of this WG proposed his collaboration to the PPR Panel on the future question on consumer exposure (MRL) from PRAPeR.

- The Scientific Committee published the opinion on a "Harmonised Approach for Risk Assessment of Compounds that are both, Genotoxic and Carcinogenic" prepared by the Gentox WG. The opinion will be presented during an EFSA/WHO International Conference with support of ILSI Europe on Risk Assessment of Compounds that are both Genotoxic and Carcinogenic - New approaches -, which will be held on 16-18 November 2005 in Brussels. Several PPR Panel members will attend this conference.
- A first meeting of the Benchmark Dose WG will be held on 16 December 2005, in Amsterdam.

9. INFO FROM DG RTD ON THE 6TH AND THE 7TH FRAMEWORK PROGRAMME

The new DG RTD E" (Biotechnology, Agriculture and Food research) desk officer in charge of pesticides and plant health, Mr. P. VENTURI, gave a presentation on what has been done during the 6th Framework programme in this area and the preparation of the 7th Framework programme. Many opportunities for agriculture/plant science are spread throughout the framework programme, and there is no specific entry for this topic. For the 7th FWP the EC proposed to double the research budget over the 7 years of the programme. Main new elements of the 7th FWP will include a simplification of its operation, research themes, establishment of European Research Council etc. There will be four specific programmes: cooperation, ideas, people, and capacities. The programme "cooperation" is within the nine main thematic priorities. European knowledge-based bio economy (KBBE) has to be built. A launch Conference for the 7th FWP will probably take place in December 2006.

Mr. Venturi informed that there are still panel evaluators for project proposals for 7th FWP needed. He encouraged the PPR Panel members to register for this task.

10. MISCELLANEOUS

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

The call for experts for the all the EFSA Panels including the PPR Panel and the new Panel on Plant Health (PLH Panel) should be published in the Official Journal on 22 November 2005, as well as put on the EFSA web. As in the past, online application is recommended and the closing date will be 07 January 2006. All Panel members wishing to participate to the next PPR Panel will have to reapply. The daily *per diem* for the members of the next Panels will be increased.

- **The PPR Panel's page on EFSA's website**

The EFSA Secretariat is elaborating some text to be put on the EFSA PPR website in order to give some basic information on pesticides, risk assessment, the role of

the Panel etc. A draft of this text will be circulated among the Panel members in due time.

The 15th PPR Plenary meeting will take place on **14-15 December 2005 in Parma**
starting 14 December 2005 at 13 h.