



**MINUTES OF THE 11TH PLENARY MEETING
OF THE SCIENTIFIC PANEL ON PLANT HEALTH, PLANT
PROTECTION PRODUCTS AND THEIR RESIDUES**

HELD IN PARMA ON 6 APRIL 2005

(Adopted by written procedure on 13 Mai 2005)

AGENDA

#	Items
1.	Welcome, apologies for absence
2.	Adoption of the agenda
3.	Feedback on the questions on pirimicarb
4.	Feedback on the question on the assessment of the acute and chronic risk to aquatic organisms
5.	General discussion on future questions addressed to the Panel, self-tasking, prioritisation: <ul style="list-style-type: none">• new fate question• presentation: improvement of the relationship between ecotox and fate in the environmental risk assessment• future cooperation between PRAPeR and the PPR Panel on assessment of Guidance Documents
6.	Feedback from the Scientific Committee, WGs Exposure and Gentox, meeting of an ad hoc WG on the interface between RA and RM
7.	Delivery of new conclusions in the Peer review of the risk assessment of the second list of active substances by the PRAPeR sector of EFSA (trifluralin, glufosinate, tolylfluanite)
8.	Feedback requested on the Commission proposal for the structure of the 7 th Framework Programme of R&D
9.	Miscellaneous

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. A. MORETTO, Mrs E. MOURKIDOU-PAPADOPOULOU-, Mr. E. PETZINGER, Mr. A. SCHAEFFER, Mr. J. STENSTRÖM, Mr. W. STEURBAUT, Ms. D. TSIPI-STEFANITSI and Ms C. VLEMINCKX.

Apologies

Mr. O. MEYER and Mr. K. SAVOLAINEN

EFSA

Mrs. DUNIER-THOMANN, Ms. Christine FUELL, Mrs. E. CEGLARSKA and Ms. M. MESNAOUI

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1. WELCOME, APOLOGIES FOR ABSENCE

The Chairman, Mr. A. Hardy, welcomed the participants to the EFSA facilities in Parma, apologies had been received from two members. The new members of the PPR Panel secretariat, Ms. C. FUELL and Mrs. E. CEGLARSKA introduced themselves.

2. ADOPTION OF THE AGENDA

The agenda was adopted without changes.

The Chairman informed the group that after the adoption of the opinion on variability of residues at the 16 February 2005 plenary meeting, Mr. A. Hart presented the opinion to the member states' representatives at the Standing Committee on the Food Chain and Animal Health/WG Phytopharmaceutical section-Residues of pesticides. The work of the PPR Panel was acknowledged and warmly thanked; the conclusions will be taken into account for the preparation of the Commission/EU position at the next Codex alimentarius meeting on 18 April 2005 (Den Hague, NL). A. Hart might give a similar presentation there.

3. FEEDBACK ON THE QUESTIONS ON PIRIMICARB

The terms of references on pirimicarb (a self-tasking question at the request of the PRAPeR sector of EFSA) were formally accepted by the chairman on behalf of the EFSA PPR Panel. The deadline for submission for adoption of the opinion is in summer 2005. The rapporteurs presented the state of the art and the outcome of the detailed discussion during the Ecotoxicology WG meeting on 5 April 2005, the first question referring to discussions started at an OECD workshop in 1996 and the "time-quotient-approach", the second question dealing with the acute risk to birds.

Further comments made by the PPR Panel will be taken into account in the further development of this opinion. The location and dates of the next Ecotoxicology WGs:

- on 19 May and on 15 June 2005 in Brussels;
- on 5 July 2005 in Parma.

4. FEEDBACK ON THE QUESTION ON THE ASSESSMENT OF THE ACUTE AND CHRONIC RISK TO AQUATIC ORGANISMS

The question on the assessment of the acute and chronic risk to aquatic organisms with regard to lowering the assessment factor if additional species are tested (another self-tasking question at the request of the PRAPeR sector of EFSA) was formally accepted by the chairman on behalf of the EFSA PPR Panel. The deadline for submission for adoption of the opinion is September 2005. The rapporteur presented the state of the art and the outcome of the detailed discussion during the WG Ecotox meeting on 5 April 2005, especially on the uncertainty factor applied to acute tests with fish and other aquatic organisms. The rapporteur will make a detailed outline on how to structure this opinion and which statistical approach to use. The PPR Panel also discussed the potential impact of this opinion for regulators as well as industry. The PPR Panel will be informed about the participation of additional *ad hoc* experts, first within a small, restricted Ecotoxicology WG on 12 May 2005 in York to launch the statistical work, followed by two regular Ecotox WGs on 19 May and 15 June 2005 in Brussels.

5. GENERAL DISCUSSION ON FUTURE QUESTIONS INCLUDING SELF-TASKING

- New questions expected (self-tasking PRAPeR):
 - Fate: A draft terms of reference for a question concerning the default Q10 value used to describe the temperature effect on transformation rates of pesticides in soil, submitted to the PPR Panel by the PRAPeR sector of EFSA (from 16th EPCO Expert Meeting) was discussed and agreed by the PPR Panel. Rapporteurs were identified and a first Fate WG will take place on 31 May 2005 in Brussels, followed by another one on 7 July 2005 in Parma.
 - Ecotox: Mr. H. Bruno, the Scientific Coordinator of the PRAPeR sector informed Panel members about the outcome of the 17th EPCO Expert Meeting where the MS experts concluded that the PPR Panel should be consulted for an opinion on the full aquatic risk assessment, especially the use of the microcosm study for cyprodinil.
 - It is very likely that further questions will come up from future EPCO Expert Meetings in the peer review process. The Scientific Coordinator of the PRAPeR sector reminded the Panel members of the mandatory one year period for issuing the EFSA conclusions (according to the legislation), which includes the integration of the EFSA opinion (requiring 6 months on average). Due to the strict time constraint those questions should be treated with high priority.
- Guidance Documents:

A table with a list of potential questions concerning Guidance Documents in preparation within Commission was discussed but the timing is still uncertain. Mr. M. Walsh explained that the Commission will issue a note where there will be a transition period for the responsibility of the Guidance Documents (GD) dealing with risk assessment, i.e., work on GD already started by the Commission will be finished by them, but the

Commission requests that all other guidance documents will become EFSA's responsibility, i.e. revision of existing documents and preparing new ones when needed. A meeting between Commission and EFSA will be useful to clarify this issue and agree on the timing; the Chairman requested to be invited in order to be able to reflect on the best use of the limited resources of the Panel.

In the ongoing process of the revision of the Directive 91/414/EEC, those GD may have their legal ground strengthened (currently MS only have to take note in the Standing Committee). Questions on the current amendment of the different areas of the Annex II and III of Directive 91/414/EEC are also expected to be submitted to the Panel.

- Discussion on self-tasking within the Panel:

The PPR Panel intensively discussed potential self-tasking issues, i.e., suitable important scientific topics to be dealt with in the future and elaborated a list of these issues. This list will be circulated to the Panel members for further consideration and for prioritisation of about three or four major topics of European interest. Meanwhile, those requests will be treated as "lower priority" *versus* requests from Commission and PRAPeR, which are in a legal and strict time constraint framework.

Mr. J. Boesten gave a presentation on "Improvement of relationship between fate and ecotoxicology in aquatic and terrestrial risk assessment", suggesting this as a possible self-tasking issue. The PPR Panel could be a good platform for this since both fate and ecotoxicological expertise is included within the Panel.

A general discussion raised the issue of increasing the publicity and scientific impact of the principles within adopted opinions, particularly the generic ones. In addition to the EFSA website, public and MS competent authorities should be better informed.

6. FEEDBACK FROM THE SCIENTIFIC COMMITTEE, WG EXPOSURE AND GENTOX

Feedback was given by the chairman on the work of the Scientific Committee and their WGs. A meeting of an ad-hoc WG on the "Interface between risk assessment and risk management" will take place in June 2005 to finalise the work started by the EU Workshop in September 2003 in the Netherlands, and two PPR Panel members will attend.

- Mr. A. Hart gave feedback on the state of the work of the Working Group Exposure on their guideline document.

- Mr. D. McGregor informed the PPR Panel about the finalisation of the draft opinion on a "Harmonised Approach for Risk Assessment of Compounds that are both Genotoxic and Carcinogenic" by the GENTOX WG, which will be on the EFSA website for 6 weeks public consultation from around 14 April 2005. Panel members' comments will be collected by mid-May by Mr. D. McGregor to be considered by the WG GENTOX and the

Scientific Committee after the public consultation. Panel members expressed surprise that they had not had the opportunity to comment on the document before it was made public.

7. DELIVERY OF THREE NEW CONCLUSIONS IN THE PEER REVIEW OF THE RISK ASSESSMENT OF THE SECOND LIST OF ACTIVE SUBSTANCES BY THE PRAPER SECTOR OF EFSA

The PPR Panel were provided for information three new conclusions on trifluralin, glufosinate and tolylfluanite finalised on 14th March by the PRAPeR sector of EFSA on the Peer Review of the risk assessment of active substances of the second list of active substances. If any PPR Panel members wish to comment on these conclusions, these should be sent directly to the Scientific Coordinator of the PREPaR.

8. FEEDBACK REQUESTED ON THE COMMISSION PROPOSAL FOR THE STRUCTURE OF THE 7TH FRAMEWORK PROGRAMME OF R&D

The Chairman presented apologies from Mr. R. Hardwick from the Commission (DG RTD), who was not able to attend the meeting to give a presentation due to other commitments. The PPR Panel members took note of the documents circulated to inform them on the preparation of the forthcoming 7th Framework Programme of the EU community for research, technological development and demonstration activities (2007-2011). They are looking forward to welcoming Mr. Hardwick in a future plenary meeting. A doubling of the budget is expected to fund research projects and infrastructure compared to the 6th Framework Programme.

9. MISCELLANEOUS

- EFSA Extranet: the chairman encouraged all Panel members to use this EFSA document management system (DMS) to download the documents related to the questions, especially useful for big files over 3 MB which pose problems to be circulated electronically. A notification will be sent automatically each time the secretariat adds a document via a voluntary subscription.

- EFSA criteria for holding meetings outside Parma: the Chairman explained EFSA policy (referring to a recent note from the Deputy-Director), the plenary meetings should in principle be held in Parma while more flexibility could be allowed for WG if small and geographically limited (meeting facilities free of charge e.g. Brussels or Panel member's place of work), the general meeting cost should not be higher than when meeting at EFSA in Parma. The proposal of holding a plenary meeting in Krakow (POL) in September was

turned down, it should be held in Parma probably 15 September 2005 afternoon/16th morning. Members emphasised concern that their additional travel time (“dead time”) should be a factor in considering possible locations for WG and Plenary meetings of the Panel.

- Update on declaration of interest: the Panel members were reminded to renew their annual declaration of interest (mandatory) by end of April 2005. They were also reminded that according to the Guidance on declaration of interest, adopted by the Management Board on 16 December 2004, each Panel member and each *ad hoc* expert has the responsibility to update it when his/her situation changes during the year (May 2005-May 2006). A discussion followed on the meaning/limit of “interest”, the EFSA legal service should be contacted directly by the Panel members for specific questions.
- The EFSA secretariat informed the PPR Panel on the preparation of the third EFSA Colloquium on European Food Consumption Database: Current and medium-to long-Term strategies to be held in Brussels on 28-29 April 2005.
- The EFSA secretariat informed (hyperlink address provided) about the ongoing EU pesticides thematic strategy (DG RTD).
- Mr. M. Maroni informed the Panel that he had contact with the organisers of the next world congress of toxicology to be held in Montreal (CA) in 2007, in May. It was agreed that K. Savolainen and he will propose to the steering committee to take the lead for a session on toxicology related to food safety.
- Information was requested on copyright when publishing scientific papers using data presented in published opinions.

The plenary meeting planned for **01 June was cancelled** since intense work will continue in the working groups. The next plenary meeting will be held on **06 July 2005** in Parma, accompanied by two Working Group meetings (Ecotox WG before and Fate WG after).