

PANEL ON PLANT PROTECTION PRODUCTS AND THEIR RESIDUES

**40th PLENARY MEETING OF THE SCIENTIFIC PANEL ON
PLANT PROTECTION PRODUCTS AND THEIR RESIDUES
HELD IN PARMA ON 9-10 SEPTEMBER 2009**

(ADOPTED BY WRITTEN PROCEDURE ON 5 OCTOBER 2009)

#	Items
1.	Adoption of the agenda, apologies for absence, declarations of interest
2.	Feedback from the Joint WG on Guidance Document birds & mammals
3.	Information regarding the revision of the Guidance Documents aquatic and terrestrial ecotoxicology
4.	Information on the Guidance Document on persistence in soil
5.	Information on the development of the new Guidance Document on emission from protected crop systems (greenhouses and cultivations grown under cover)
6.	Information on the evaluation of the toxicological relevance of metabolites and degradates of pesticide active substances for dietary risk assessment Guidance Document
7.	Information on the development of the guidance document on the probabilistic methodologies for modelling dietary exposure to pesticide residues
8.	Information on the development of the new Guidance Document for pesticide exposure assessment for workers, operators, bystanders and residents-comments received from Public Consultation
9.	Cumulative risk assessment: Identification of cumulative Assessment group
10.	Information on issues regarding the variability factor in acute dietary exposure assessment.
11.	New questions from Commission/self-task: <ul style="list-style-type: none"> • FOCUS groundwater
12.	Miscellaneous: <ul style="list-style-type: none"> • Feed-back from the Scientific Committee and its Working Groups • Discussion on Opinion transparency • Information on results of the expert satisfaction survey 2008 and INEX update (by R. Maijala) • Template for opinion / new EFSA Journal (by C. Sondermann) • Demo on functioning of the EFSA Extranet (by I. Inverardi) • Debriefing on Pesticide Steering Committee meeting 8-9 September.

PANEL ON PLANT PROTECTION PRODUCTS AND THEIR RESIDUES

PARTICIPANTS

Members of the PPR Panel

Ms. A. ALIX, Mr. J. BOESTEN, Ms. C. BOLOGNESI, Mr. E. CAPRI, Mr. A. HARDY (Chairman), Ms K. HIRSCH-ERNST, Ms. S. HOUGAARD, Mr. R. LUTTIK, Mr. A. MORETTO, Ms. A. PETERSEN, Ms. Y. PICO` , Mr. A. SCHAEFFER, Mr. P. SOUSA, Mr. W. STEURBAUT, Ms. M. TASHEVA, Mr. T. VAN DER LINDEN, Ms C. VLEMINCKX.

Apologies

Mr. A. HART, Ms. B. OSSENDORP, Mr. X. PAVARD (DG SANCO O3), Ms. A. STROMBERG, **EFSA**

PPR Panel secretariat: Ms. M. DUNIER-THOMANN, Ms. C. FÜLL, Ms. K. NIENSTEDT, Ms S. BOPP, Mr. M. EGSMOSE, Mr. L. MOHIMONT, Mr. I. SEBESTYEN, Mr. H. STEINKELLNER, Ms. G. BOSCHETTO, Ms. A. PASQUIN, Ms. J. RICKETTS.

R.MAIJALA Director RA, D. MAURICI SC, C. SONDERMANN SCO, I. INVERARDI IT

1. ADOPTION OF THE AGENDA, APOLOGIES FOR ABSENCE, DECLARATIONS OF INTEREST

The agenda was adopted without changes; apologies were received from 3 Panel members and Xavier PAVARD.

In accordance with EFSA's policy on Declarations of Interest, EFSA screened the ADoI filled in by the Panel members invited to the meeting. No conflicts of interest related to the issues discussed in this meeting were identified during the screening process and no new interests were declared in the SDoI or at the beginning of this meeting.

2. FEEDBACK FROM THE JOINT WG ON GUIDANCE DOCUMENT ON BIRDS & MAMMALS

Before the meeting, the participants had received the "Report from the Joint WG on the Guidance Document on Risk Assessment for Birds & Mammals", a related covering note and a draft review questionnaire to be potentially used by competent authorities in order to check how the revised GD is working after about two years. C. FÜLL gave a presentation on the outcome of the Joint WG and the next steps.

The last and final meeting of the Joint WG took place on 8 July, all remaining tasks were followed up and all necessary decisions taken. The Joint WG has produced a report that contains all the main decisions. On the basis of this report a drafting group of three people was tasked by the Joint WG to apply these decisions, revisit the PPR Panel opinion and to produce the revised GD. The SCFCAH will receive the Joint WG's report and C. FÜLL will give a presentation at their meeting on 2 October. The SCFCAH is requested to discuss and evaluate the submitted documents and send any comments to EFSA within 9 October. Meanwhile, the editorial team will implement the decisions, revise the GD, circulate the draft to the Joint WG for comments and submit a final version of the revised GD to the SCFCAH by 30 October.

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If the SCFCAH agrees to take note of the revised GD during their meeting on 26-27 November, publication of the revised GD is foreseen by end 2009 (early 2010) with implementation six months later. The document will be published as an EFSA document with a link on the Commission's website.

The Panel members stated that they would like to see their work and contributions properly acknowledged in the revised GD. This will be accomplished by referring to the respective Panel opinion on the Science behind the GD on RA for birds & mammals.

Regarding the identified need for five further opinions related to the RA for birds and mammals (two high priority, one medium, two low priority) it is unclear when the work on these opinions could start due to the new PPR Unit situation (see item 12).

3. INFORMATION REGARDING THE REVISION OF THE GUIDANCE DOCUMENTS ON AQUATIC AND TERRESTRIAL ECOTOXICOLOGY

EFSA staff informed the Panel about the status of the work. The joint WG and the Ecoregions WG last met before the 39th Plenary and no progress was made during the summer break regarding the work of these WGs. Both WGs have meetings scheduled for September after the plenary meeting.

Specific Terms of Reference (TOR) were proposed to be issued for both WGs: one for the WG Ecoregions for developing the concept further, and one for the joint WG on Ecotoxicological Effects for the preparation of a draft opinion on protection goal proposals, which would be available for consultation by the end of 2009. The intention is to consult this draft opinion with risk managers and through a stakeholder workshop during the 1st quarter of 2010. The Panel agreed on the proposed TORs.

The Panel discussed implications on the work plan regarding the potential transfer of EFSA staff from the PPR unit to the PRAPER unit for 6 to 9 months in 2010. The work planned for 2010 regarding the joint WG may be delayed. Regarding the specific work, the activities related to one of the two GDs (either aquatic or terrestrial ecotox) will need to be frozen for one year.

4. INFORMATION ON THE GUIDANCE DOCUMENT ON PERSISTENCE IN SOIL

The Chair of the WG informed the Panel about the status of the work. The WG met on the 16/17 June and a WG meeting was held at JRC on 30 June concerning supplementary data-support from JRC. Tiered approach for exposure assessment for annual crops, conventional/reduced tillage and spray application is taking form. Scenarios for Northern, Central and Southern Europe for total content and pore water have been selected. An opinion is scheduled for adoption by the end of this year. The WG will meet again on 16/17 September. The Panel was also informed about a visit to US-EPA and Health Canada Fate/Environmental teams by a Panel member and a representative from the PPR unit to give an update on EFSA's guidance work and exchange of scientific methodologies in Europe, USA and Canada.

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5. INFORMATION ON THE DEVELOPMENT OF THE NEW GUIDANCE DOCUMENT ON EMISSIONS FROM PROTECTED CROP SYSTEMS (GREENHOUSES AND CULTIVATIONS GROWN UNDER COVER)

The chair of the WG updated the Panel on the ongoing work in the WG on Emissions from Protected Crops. The first data collection on greenhouse structures is close to finalisation. Final reports and databases should be delivered by the contractors within September 2009. Another call for a second data collection to fill already known data gaps closed on 1 September. Received offers will be evaluated by end of September.

A draft programme for the stakeholder workshop PROTEA, which will take place in Parma on 17-19 November, was developed and will be finalised in the WG meeting on 10/11 September. WG members will be actively involved by giving presentations and as session chairs. Online registration was open until 10 August. Due to a limited number of places 65 participants will be invited, covering 19 countries, 14 MS regulatory authorities, representatives of academia, industry, consultancy and associations.

The chair of the WG also reported on the planned output (reports and opinions) for this WG. The WG on Emissions from Protected Crops will meet again on 10/11 September.

6. INFORMATION ON THE EVALUATION OF THE TOXICOLOGICAL RELEVANCE OF METABOLITES AND DEGRADATES OF PESTICIDE ACTIVE SUBSTANCES FOR DIETARY RISK ASSESSMENT GUIDANCE DOCUMENT

The secretariat informed the Panel that 3 new members joined the WG on the toxicological relevance of metabolites. During the last meeting of this WG, 2 rapporteurs volunteered to cover the toxicological and residue parts of the mandate and they were confirmed by the Panel members.

The final report of the Grant Agreement on the applicability of the Threshold of Toxicological Concern (TTC) concept has been evaluated and endorsed by the Steering Committee. The interim reports of the other 2 outsourced projects (Applicability of QSAR analysis and Impact of Metabolism on Toxicity) were also discussed by the respective Steering Committees and some reshaping of these projects was agreed as a consequence of the outcome of the TTC project.

A draft structure of the opinion has been submitted by the chair of the WG and this will be further developed by the WG on the Toxicology of Pesticides. The next meeting of the WG on the toxicological relevance of metabolites is planned to take place in February 2010 and will benefit from the outcome of all outsourced activities.

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7. INFORMATION ON THE DEVELOPMENT OF THE GUIDANCE DOCUMENT ON THE PROBABILISTIC METHODOLOGIES FOR MODELLING DIETARY EXPOSURE TO PESTICIDE RESIDUES

The secretariat informed the Panel that 3 new members joined the WG on probabilistic methodologies, while 3 others from the previous PPR Panel left.

The last meeting of the WG agreed that, as a guidance document intended for trained users, the final product would be concise, clear, and well scoped to regulatory purpose. It was therefore decided that eventual areas requesting background information, clarification or development, but not needed for implementing the guidance, would be dealt with separately (either as an opinion or annexes). Five regulatory scenarios will be covered by the guidance document, reflecting the experience acquired by the Panel in the Cumulative Risk Assessment of triazole fungicides.

The WG intends to present a first complete draft of the guidance document during the October plenary meeting. The public consultation should be launched in January 2010.

8. INFORMATION ON THE DEVELOPMENT OF THE NEW GUIDANCE DOCUMENT FOR PESTICIDE EXPOSURE ASSESSMENT FOR WORKERS, OPERATORS, BYSTANDERS AND RESIDENTS- COMMENTS RECEIVED FROM PUBLIC CONSULTATION

The secretariat gave a short overview of the background of the opinion and previous activities. The draft opinion/guidance document has been posted on the EFSA homepage for public consultation, which ends on 15 September. After that, EFSA will distribute the comments received from the different stakeholders to the experts. The draft report on the public consultation, also containing responses to the comments, should be ready for distribution to the experts by 23 October for further discussion at the Toxicology WG meeting on the 29-30 October. The report of the public consultation will then be published on the EFSA website. The proposed deadline for adoption of the opinion is still April 2010.

A rapporteur and a co-rapporteur were appointed by the Panel.

9. CUMULATIVE RISK ASSESSMENT: IDENTIFICATION OF CUMULATIVE ASSESSMENT GROUP

The Toxicology of Pesticide WG has discussed the draft ToR sent out ahead of the meeting by the EFSA secretariat and amended parts of it for final agreement at the Plenary meeting. After a discussion, the Panel Members accepted the revised Terms of Reference to be sent to the Executive Director.

A Rapporteur volunteered and will be appointed for this mandate, as agreed by the Panel.

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10. INFORMATION ON ISSUES REGARDING THE VARIABILITY FACTOR IN ACUTE DIETARY EXPOSURE ASSESSMENT.

The Panel was informed that the US EPA is considering sending a letter to EFSA on possible cooperation regarding the use of variability factors in probabilistic modelling. The issue would probably require outsourcing to investigate its impact according to European exposure scenarios, but merits full consideration as the Panel is currently developing guidance on probabilistic methodologies. The Panel would support a positive answer to this international cooperation.

11. NEW QUESTIONS FROM COMMISSION/SELF-TASK.

Due to the new situation regarding the PPR Unit staffing in 2010 (see item 12), the start of work on the opinion on the FOCUS Groundwater will be postponed until the return of the scientific officer in charge in the Unit. No new questions could be accepted in sectors where resources are not sufficient to allow the secretariat to support the Panel.

12. MISCELLANEOUS:

- Feed-back from the Scientific Committee and its Working Groups

T. Hardy gave an overview on the latest developments at the SC held in July (e.g.WG on Nanotechnologies, Statistical approaches in RA, Genotoxicity). The WG on Human Heath Benefit Assessment of Food informed participants about a Workshop at the end of October (EU project DG RTD).

The PPR Panel members were asked to join the new WGs if they could fit in this extra work load; one toxicologist volunteered to attend the WG on Genotoxicity.

- Discussion on the SC Opinion on transparency

D MAURICI (SC) gave a presentation on the adopted opinion on transparency (August 2006). EFSA scientific outputs need to be transparent with regard to data, methods of analysis and assumption used in the risk assessment.

- Information on results of the expert satisfaction survey 2008 and INEX update

The results of the 2008 expert satisfaction survey were detailed by the Director of RA, in particular the top/bottom 10 items for the PPR Panel.

Then R. MAIJALA gave an overview on the INEX evaluations (self-review, internal and external review). The selection for external reviewers has been completed and the experts will start to review the opinions adopted during the current year in October.

She also explained the EFSA policy and procedure on declarations of interest (Annual and Specific).

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- Debriefing on the Pesticide Steering Committee meeting 8-9 September

The Director of RA, R.MAIJALA, explained the decision of the Executive Director and senior management taken in early September regarding the provisional transfer in 2010 of some scientific staff from the PPR Unit to PRAPeR unit (for 9 months) in order to help the PRAPeR Unit meet the tight deadlines of delivery of EFSA Conclusions on active substances. The high number of re-submission of dossiers by industry does not allow the PRAPeR unit to face the workload with their current resources and relevant expertise is available in the PPR Unit and other SCA Directorate units.

In order to better understand the consequences on the PPR work programme 2010, M. DUNIER THOMANN gave the same presentation she presented in the morning to Member States at the Pesticide Steering Committee (the Chair of the PPR Panel also attended the PSC). The preparation of some Guidance Documents will be stopped/frozen during the duration of the absence of the scientific officers in charge of the relevant WGs. In this context new questions from the Commission will be difficult to accept and the start of new Guidance Documents will be postponed. Moreover, the spring stakeholders Ecotoxicology Workshop needs to be reconsidered.

Member States at the June Pesticide Steering Committee were asked to submit a priority list of new GDs to be developed by the PPR Panel: they already sent some proposals which were detailed on 9 September morning. Under the new circumstances none of these new tasks could be envisaged to start.

A letter will be sent to Member States to ask them to make their best efforts to second DNEs to EFSA for the relevant period.

An animated discussion followed this presentation where Panel members expressed their serious concerns regarding the freeze and postponement of the adoption timeframe foreseen for some ongoing GDs, including the postponement of the start of the FOCUS groundwater opinion.

The Chairman informed the Panel that he will send a letter to the Executive Director to address the concerns of the Panel members.

- Template for opinion / new EFSA Journal

C. SONDERMAN gave a presentation on the new online EFSA Journal which will be launched at the end of 2009. The Journal will be cited in bibliographic data bases and will be used for the publication of all scientific outputs (opinions, GD, reports). It will be managed by an EFSA editorial board.

A new template will be used from now onwards and a small Abstract will be added.

- Demo on the functioning of the EFSA Extranet

I. INVERARDI gave a presentation on the functioning of the EFSA Extranet especially for new Panel members. Service desk can be contacted for assistance.

The next Plenary meeting will take place on **28/29 October 2009** in Parma, starting at **14h00 on 28 October**.
