

PLANT PROTECTION PRODUCTS AND THEIR RESIDUES

**34TH PLENARY MEETING OF THE SCIENTIFIC PANEL ON
PLANT PROTECTION PRODUCTS AND THEIR RESIDUES**

HELD IN PARMA ON 23RD-24TH SEPTEMBER 2008

(ADOPTED BY WRITTEN PROCEDURE ON 5 NOVEMBER 2008)

#	Agenda
1.	Adoption of the agenda, apologies for absence, declarations of interest
2.	Presentation of draft opinion on the risk assessment for cumulative exposure to triazoles-contract negotiated procedure (report from the contract)
3.	Presentation of draft opinion on deltamethrin
4.	Information on the report of the contractor (Art. 36) on the Guidance Document for pesticide exposure assessment for workers, operators, bystanders and residents
5.	Information on the development of a new Guidance Document on emission from protected crop systems (greenhouses and cultivations grown under cover)
6.	Presentation of the draft Guidance Document on persistence in soil
7.	Presentation of the work plan for the opinion on pore water concentrations as metrics for the assessment of ecotoxicological effects in soil
8.	New mandate on probabilistic methodologies for consumer exposure assessment
9.	New mandate on the toxicological burden of pesticide metabolites in food commodities (info on the contracts under Art. 36)
10.	Information on the workplan for new Guidance Documents to revise or develop
11.	Presentation of some relevant programmes under the 6 th and 7 th Framework programme: J.F. Maljean, DG RTD Dir. E
12.	Miscellaneous: <ul style="list-style-type: none"> • Feed-back from the Scientific Committee and Working Groups • Opinion on transparency • New development in the finance unit • Comments on the EFSA workplan 2009-2013 • Media handling guidelines • Evaluation of the EU pesticide safety review process • Information on the expert survey • Other items

PARTICIPANTS

Members of the PPR Panel

Mr. D. BARCELLO-CUILLERES, Mr. J. BOESTEN, Mr. A. BOOBIS (on 23rd only), Ms. C. BOLOGNESI (on 23rd only), Mr. A. BUCHERT, Mr. E. CAPRI, Mr. D. COGGON, Mr. A. HARDY (Chairman), Mr. A. HART, Mr. M. LIESS, Mr. R. LUTTIK, Mr. O. MEYER, Ms. S. MICHAELIDOU-CANNA, Mr. A. MORETTO (on 24th only), Mr. M. MÜLLER, Ms. B. OSSENDORP, Mr. W. STEURBAUT, Ms. M. TASHEVA, Ms C. VLEMINCKX.

Apologies

Mr. H. KÖPP, Mr. M. MONTFORTS, Mr. X. PAVARD (DG SANCO O3)

EFSA

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

For item 12 only: Ms. M. VARHO (Finance Unit) and Mr. C. WOLFF (Legal and Policy Unit), Mr. STEINKELLNER (PRAPeR unit).

Commission

Mr. J.F. MALJEAN (DG RTD E)

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

The agenda was adopted without changes, apologies were received from two members for the whole meeting, one who was not attending on 23rd and two who were not attending on 24th September. The Chairman welcomed the new staff of the PPR Unit: Ms. RICKETTS (secretariat), Ms S. BOPP (scientific officer environment) and Mr. STEINKELLNER (toxicologist PRAPeR) who will join the unit on 1st October.

Declarations of interests: interests were declared by Mr. J. BOESTEN, Mr. A. BOOBIS, Mr. D. COGGON, Mr. A. HART, Ms. B. OSSENDORP, Ms. M. TASHEVA, referring to the Annual/Specific D of I.

2 PRESENTATION OF DRAFT OPINION ON THE RISK ASSESSMENT FOR CUMULATIVE EXPOSURE TO TRIAZOLES-CONTRACT NEGOTIATED PROCEDURE (REPORT FROM THE CONTRACT)

The Rapporteur of the toxicological part informed the Panel Members about the discussion on the joint meeting that took place before the Plenary, the planned layout

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and content of the opinion and the structure of the opinion. The Rapporteur of the residue part informed everyone about the present state of work and that calculations will be ready for the next WG meeting. The Rapporteur gave detailed information about the Steering Group meeting on 22nd September 2008, when the final report presented by the contractor was accepted with some amendments. The Panel discussed the possibilities of the report being published.

3 PRESENTATION OF DRAFT OPINION ON DELTAMETHRIN

The Rapporteur made a short presentation about deltamethrin, and the results of relevant studies. The Toxicology WG meeting had discussed the details of the opinion before the plenary meeting and agreed the answers to the questions. The next version of the draft opinion will be discussed in October and then it will be circulated to the Panel members for comment before the adoption in December.

4 INFORMATION ON THE REPORT OF THE CONTRACTOR (ART. 36) ON THE GUIDANCE DOCUMENT FOR PESTICIDE EXPOSURE ASSESSMENT FOR WORKERS, OPERATORS, BYSTANDERS AND RESIDENTS

The Rapporteur made a short presentation about the possible outcome of the outsourced project and the problematic areas identified by the contractor. Publishing of the report on the EFSA website should be agreed with the contractor. The final report will be submitted at the beginning of October and the Steering Group will discuss and decide whether the final version is acceptable during their meeting in London (17th October).

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

The Chairman of the WG gave an update on the development of the work. The WG met on 16-17th June and 9-10th of September. A draft project plan has been further developed and is scheduled for public web consultation in October.

The WG met with EUROSTAT in July for collection of data on the type and abundance of protected crop systems in Europe. Data has been received from EUROSTAT. Additional data is needed and will be collected through an EFSA procurement that will be launched in autumn.

6 PRESENTATION OF THE GUIDANCE DOCUMENT ON PERSISTENCE IN SOIL

The Chairman of the Fate WG presented the progress of the work. The WG had met on 18-19th June. Meetings were held in July with ad-hoc experts and the WG met again on 10-11th September. An important topic discussed in the WG has been the methodology for scenario development including considerations of including soil,

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weather and if possible biology of soil-living organisms in the selection. EFSA is developing a formalised collaboration agreement with JRC to support cooperation and data-exchange. The collaboration agreement will be signed by the two parties on 10th November. For specific tasks for support from JRC to EFSA, individual agreements will be set up under this collaboration agreement.

7 PRESENTATION OF THE WORK PLAN FOR THE OPINION ON PORE WATER CONCENTRATIONS AS METRICS FOR THE ASSESSMENT OF ECOTOXICOLOGICAL EFFECTS IN SOIL

The 1st draft opinion corresponding to the mandate was circulated on 12th September to all Panel Members for their comments.

During the Plenary meeting, a presentation was given explaining the structure and general outcome of the scientific opinion. Comments were received from 2 Panel Members in written form. Additionally, more comments were given orally and discussed in the Plenary. It was concluded to amend the draft and to discuss it at the next Plenary in December.

8 NEW MANDATE ON PROBABILISTIC METHODOLOGIES FOR CONSUMER EXPOSURE ASSESSMENT.

The Panel adopted the Terms of References for a new mandate (Self tasking) to provide guidance on how probabilistic methodologies can be used for estimating dietary exposure, as tools additional to deterministic methods, in the authorisation of plant protection products, in MRL-setting and in the assessment of actual exposure based on residue-monitoring data. The rapporteur justified the interest of this new mandate by the scientific need of this tool allowing higher Tier exposure assessments and the experience gained by the current Panel in this area. The Panel also agreed on the composition of the working group. The objective is to finalise this mandate by the end of the current mandate (mid 2009), including a public consultation in 2009.

9 NEW MANDATE ON THE TOXICOLOGICAL BURDEN OF PESTICIDE METABOLITES IN FOOD COMMODITIES.

The Panel adopted the Terms of Reference for a new mandate (Self tasking) to develop an opinion on approaches to evaluating the toxicological relevance of metabolites and degradates of pesticide active substances in dietary risk assessment. The Panel was informed on the progress in the 3 outsourced exploratory scientific activities. The Panel agreed on the composition of the steering committees for the project related to the applicability of TTC concept, and for the project on the impact of metabolic processes on the toxicological properties of active substances. No proposals were made for the project on QSAR analysis and the Panel agreed that ad-hoc members could be designated to follow these projects and help Panel Members, in view of the current intensive workload.

10 INFORMATION ON THE WORKPLAN FOR GDS TO DEVELOP OR REVISE

The EFSA Secretariat informed Panel Members about the planned work on the Guidance Documents “Aquatic Ecotoxicology SANCO/3268/2001” and “Terrestrial Ecotoxicology SANCO/10329/2002”. A procurement for literature reviews in certain areas was launched in August 2008 and a public consultation on both documents is planned for 15th October-15th December 2008. A questionnaire regarding the scope of the revision will be sent to risk managers of the national competent authorities in the Member States. During a first kick-off meeting initial ideas to be considered for the revision process were collected. The group agreed that the two existing documents will be kept as (at least) two separate documents, although the revision process will start off with the WG “Ecotoxicological effects” because of the need of harmonisation between the different scientific areas. This WG will meet in November 2008 with the aim of discussing the ideas compiled at the previous meeting and the further organisation, including the preparation of a provisional workplan and the operating schedule.

The Panel discussed the Draft Terms of Reference for Revision of the Guidance Document on Dermal Absorption (Sanco/222/2000 rev. 7). A toxicologist from the PRAPeR Unit informed the Panel about the background to the question. The Panel discussed and agreed the terms of reference and the timeline.

The Panel discussed the wider role of the Panel in the revision of guidance documents and the procedures for revision. Some members expressed the view that the best use of the Panel members’ expertise would be that of identifying the relevant scientific issues behind the GD. The actual writing of the GD, very time consuming, might be better externalised and coordinated by EFSA secretariat. As for the GD on RA for birds and mammals an opinion should be issued about the science behind the GD and then the risk management parts may be discussed with the Commission and MS to finalize the GD.

Regarding the selection of ad-hoc experts, the PPR secretariat also mentioned that the EFSA procedures (SOPs) need to be followed and that ad-hoc expert candidates need to be registered in the EFSA expert database. Additionally, a survey in the scientific community requesting recommendations of experts could be done, in order to identify potential experts who could then be invited to register in the EFSA database.

11 PRESENTATION BY J.F. MALJEAN DG RTD Dir. E

Mr. J.F. MALJEAN presented the ongoing activities and roadmap for the 6th and 7th Framework Programme (2007-2013) in the sector related to plant protection products. The new call will close on 15 January 2009. EFSA holds one meeting a year with the DG RTD officer to highlight EFSA’s priorities.

A theme on the development of models to assess the risks from exposure to pesticides to operators, workers, residents and bystanders was requested by DG SANCO and EFSA in 2006/2007 and is to be added in the 2008 Work Programme in the Health

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Sector. If this is agreed in the 2010 WP then any project would start in 2011 and finish around 2014.

12 MISCELLANEOUS

- **Feedback from the Scientific Committee and WGs**

The Chairman informed the Panel members that the next Scientific Committee meeting will be held on 25-26th September.

-WG Transparency: The final draft of the opinion on transparency will be circulated soon to Panel Members, prior to possible adoption in December. All Panels are encouraged to discuss the implementation in their area of expertise and this will be done on 10th December for the PPR Panel.

-WG Welfare of Experimental Animals: O. Meyer reported the latest developments on the preparation of the opinion on animal testing, which will be circulated before the next Plenary meeting. It is looking at alternative approaches for reduction, replacement and refinement. Both toxicology and ecotoxicology are considered.

- **New development in the finance unit**

M.Varho presented EFSA's new financial statement application to permit experts to see their statement on-line at any time.

- **Comments on EFSA's work plan 2009-2013**

The Chairman thanked the Panel Members who had commented on the work plan on time; he will report to the SC on 25-26th September. Some members added last minute comments.

- **Media Handling guideline**

The new guideline for the Panels was circulated to Panel Members before the Plenary. Ian Palombi is the Press Officer with responsibility for the work of the PPR Panel.

- **Evaluation of the EU pesticide safety review process (PRAPeR unit)**

The final report prepared by the SCA Directorate following consultation of MS, Commission, PPR unit and Panel representative (Ms C. Vleminckx) in WGs from January to July 2008 will be published in the EFSA Journal in the coming days. Four pages of text deal with Guidance Documents and were circulated for comments to the Panel at the end of June. A Steering Committee will be created in December 2008 to provide a platform for cooperation and consultation between the different actors involved in pesticide risk assessment in the EU, to plan and monitor the entire process: it will consist of representatives from MS (nominations ongoing), the Commission, the PPR unit/Panel representatives and will be chaired by PRAPeR. Some members expressed concern on the less visible assessment of the scientific quality of the PRAPeR output, in line with what it is proposed to do with the opinions of the Panels.

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- **Information on the expert survey**

A satisfaction survey will be sent to all experts working for EFSA by end of October to assess the level of satisfaction with regard to scientific, administrative and communication support.

- **Other items: Use of human data in the new regulation replacing Dir. 91/414.**

Some Panel members expressed their wish to draw to the attention of EFSA's Executive Director, in a letter sent by the Chairman, the implications of the proposed restrictions on the use of human data to assist the toxicological risk assessment of pesticides under the Council common position aimed at replacing Dir. 91/414/EEC. They also highlighted some conceptual misunderstandings of risk assessment versus hazard identification, and internal inconsistencies in the wording of the proposed new regulation, which they were concerned, had the potential to cause confusion and perhaps lead to legal challenge. Members recognised that the opportunity to influence the proposed text had closed following the 2nd reading by the European Parliament (EP) and that amendments would not now be admissible according to EP rules of procedure. However, the Panel members expressed their disappointment that they had not been consulted at an appropriate time on an important development that would have benefitted from their expert scientific input. Ms. M. DUNIER-THOMANN informed them that EFSA's comments on the Commission proposal, that were sent to the Commission in mid-2006, were prepared by EFSA's staff: PRAPeR (including their toxicologists) and PPR unit, as it is their remit to do so in relation to primary legislation. It was reminded that the Panel has no "legal" identity as it is a body inside EFSA and consequently cannot directly "lobby" EP, Commission, etc. The legal representative of EFSA is the Executive Director.

The next **PPR Plenary meeting** will take place on **9-10th December 2008** in Parma, starting at 14h00 on 9th December.