PANEL ON PLANT PROTECTION PRODUCTS AND THEIR RESIDUES

43rd PLENARY MEETING OF THE SCIENTIFIC PANEL ON PLANT PROTECTION PRODUCTS AND THEIR RESIDUES

HELD IN PARMA ON 27-28 JANUARY 2010

(ADOPTED BY WRITTEN PROCEDURE ON 23 FEBRUARY 2010)

#	Items
1.	Adoption of the agenda, apologies for absence, declarations of interest
2.	Rules of Panels, INEX 2009 and Management Plan 2010 (R. Maijala, Director RA)
3.	Adoption of the opinion on the preparation of a Guidance Document for pesticide exposure assessment for workers, operators, bystanders and residents
4.	Development of the new Guidance Document on emission from protected crop systems (greenhouses and cultivations grown under cover) – information on first draft opinion
5.	Draft opinion on protection goals: agreement of the Panel for the risk manager and stakeholder consulation of the draft opinion. Information on these consultations.
6.	Information on the revision of the guidance document Persistence in Soil
7.	Guidance Document on the probabilistic methodologies for modelling dietary exposure to pesticide residues: agreement for public consultation
8.	Information on the evaluation of the toxicological relevance of metabolites and degradates of pesticide active substances for the dietary risk assessment Guidance Document
9.	Information on the identification of pesticides to be included in cumulative assessment groups on the basis of their toxicological profile
10.	Information about the revision of the Guidance Document on Dermal Absorption
11.	Miscellaneous: • Information on procurement regarding database compilation of pesticide ecotoxicology Tier 1 study endpoints • Feed-back from the Scientific Committee and its Working Groups • Discussion of the list of new requests for Guidance Documents to be prepared by the PPR Panel submitted by MS *via* the Pesticide Steering Committee and on the Working Document DG SANCO • ECPA Comments on the triazole opinion.

European Food Safety Authority

PANEL ON PLANT PROTECTION PRODUCTS AND THEIR RESIDUES

PARTICIPANTS

Members of the PPR Panel

Ms. A. ALIX, Mr. J. BOESTEN, Ms. C. BOLOGNESI, Mr. T. BROCK, Mr. E. CAPRI, Mr. A. HARDY (Chairman), Mr. A. HART, Ms K. HIRSCH-ERNST, Ms. S. HOUGAARD BENNEKOU, Mr. R. LUTTIK, Mr. A. MORETTO, Ms. B. OSSENDORP, `, Mr. A. SCHAEFFER, Mr. W. STEURBAUT, Ms. A. STROMBERG, Ms. M. TASHEVA, Mr. T. VAN DER LINDEN, Ms C. VLEMINCKX.

Apologies

Ms. A. PETERSEN, Ms. Y. PICO, Mr. P. SOUSA, Mr. X. PAVARD (DG SANCO O3).

EFSA

Ms R. MAIJALA (Director RA)

PPR Panel secretariat: Ms. M. DUNIER-THOMANN, 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. M. SODANI, Ms. J. RICKETTS.

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

The agenda was adopted without changes; apologies were received from Ms PETERSEN, Ms PICO, Mr SOUSA and Mr 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. RULES OF PANELS, INEX 2009 AND MANAGEMENT PLAN 2010 (R. MAIJALA, DIRECTOR RA)

Ms R. MAIJALA presented an overview of work in 2009 and the priorities of the Management Plan 2010. The new rules to be applied to the Panels regarding expert indemnities and travels were detailed, and the external review in 2009 was summarised. An exhaustive discussion took place.

3. ADOPTION OF THE OPINION ON THE PREPARATION OF A GUIDANCE DOCUMENT FOR PESTICIDE EXPOSURE ASSESSMENT FOR WORKERS, OPERATORS, BYSTANDERS AND RESIDENTS

The Panel was informed about the latest changes in the opinion, and some additional clarifications were discussed. The Panel adopted the opinion. After the final editorial checking, the opinion should be published on the EFSA website within 3 weeks, in mid February. The version of the opinion with the new clarifications will be circulated for final editorial checking in the week after the plenary meeting. Final editorial comments are requested within ten days.

4. DEVELOPMENT OF THE NEW GUIDANCE DOCUMENT ON EMISSION FROM PROTECTED CROP SYSTEMS (GREENHOUSES AND CULTIVATIONS GROWN UNDER COVER) – INFORMATION ON FIRST DRAFT OPINION

The Chairperson of the WG gave an update on the development of the new GD on estimating emissions from the wide range of protected crop systems (greenhouses and covered crops). An opinion on the outline for the new guidance is tentatively scheduled for adoption in March. A draft of the opinion was presented and discussed at the Plenary. Three rapporteurs were appointed. The WG will meet on 28-29 January and again on 23-24 March.

Reports from external contractors on data-collection of protected crop systems and structure for Southern and Eastern Europe have been published on the EFSA website. An internal report for Northern Europe is under preparation together with the Coding Manual for collecting data in a harmonised approach. A second data collection covering the central regulatory zone according to EU regulation 1107/2009/EC is ongoing.

The Chairperson also updated the Panel on the PROTEA stakeholder workshop *"Pesticide emissions from protected crop systems: Are these emissions different from those in the open field?"* - held on 17-19 November 2009 in Parma. The stakeholder report is currently with the Workshop participants for comments and will be published on the EFSA website in February.

5. DRAFT OPINION ON PROTECTION GOALS: AGREEMENT OF THE PANEL FOR THE RISK MANAGER AND STAKEHOLDER CONSULATION OF THE DRAFT OPINION. INFORMATION ON THESE CONSULTATIONS.

The draft opinion on the development of specific protection goal options for environmental risk assessment of pesticides was circulated to the Panel the week before the Plenary. The draft opinion was presented and discussed, in the presence of 1 of the 3 rapporteurs, the chair of the WG, and most of the Panel WG members. The Panel made some (minor) suggestions to change the manuscript and agreed that the draft opinion is ready for being consulted in the stakeholder workshop (April 2010) and with risk managers. The next WG meeting will take place on 4-5 February.

The secretariat updated the Panel on the stakeholder workshop *"Protection Goals for Environmental Risk Assessment of Pesticides - What and where to protect?"* planned for 15-16 April in Parma. The registration was open from December 2009 until 20 January 2010. Eighty registrants were invited to participate and the others will be placed on a reserve list. The participants were selected on the basis of stakeholder group, country, expertise, and affiliating institution/company.

The secretariat updated the Panel about progress on the organisation of the risk manager consultation. Based on the latest discussions with the European Commission and Member States, the envisaged consultation process will be discussed again with the European Member States at the Pesticide Steering Committee meeting due to be held mid-February in Parma.

6. INFORMATION ON THE REVISION OF THE GUIDANCE DOCUMENT PERSISTENCE IN SOIL

The Chairperson of the WG updated the Panel members on the progress of the work. The opinion on "Outline Proposals for Assessments of Exposure in Soil" was published on the EFSA website in January.

Two additional opinions for the guidance document are scheduled for adoption in 2010. In addition 3 technical reports are planned to support the opinion. Further contracts have been signed for validation of aspects of the guidance and for the collection of information on crop interception values. The outcome of externalised work will become available in 2010. The WG will meet again on 25-26 March.

7. GUIDANCE DOCUMENT ON THE PROBABILISTIC METHODOLOGIES FOR MODELLING DIETARY EXPOSURE TO PESTICIDE RESIDUES: AGREEMENT FOR PUBLIC CONSULTATION

The Chair person of the WG updated the Panel on the latest changes to the text of the Guidance Document, in particular regarding the conclusion section which now contains a flowchart of the recommended process and a list of necessary future developments. The Panel discussed the whole document and agreed minor changes.

The Panel agreed to proceed with a public consultation of 3 months. The WG and the secretariat will review the draft opinion for last consistency checks, final editorial improvements, alignment of the glossary with previous PPR Panel opinions and formatting.

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

The secretariat informed the Panel that the final reports of the last 2 outsourced activities were provided on time by the contractors. Steering committee meetings are scheduled to consider the approval of the reports. A meeting of the WG will also take place in February in order to discuss the use of the results of these outsourced activities within the mandate and define future working strategies of the WG.

9. INFORMATION ON THE IDENTIFICATION OF PESTICIDES TO BE INCLUDED IN CUMULATIVE ASSESSMENT GROUPS ON THE BASIS OF THEIR TOXICOLOGICAL PROFILE

The work on this opinion started with an outsourced activity when the Grant Agreement was signed by the beneficiary and EFSA in December 2009. The Rapporteur informed the Panel that the kick-off meeting with the contractor took place on 26 January. During the kick-off meeting, the activities planned by the contractor were discussed and some clarifications were agreed. The timeline of the project and the dates of deliveries were agreed as well as the planned content of the interim report. The next Steering Committee meeting will be organized in June 2010 for discussion of the interim report and the further steps necessary to complete the project. The project will take 12 months and the final report is expected to be delivered in December 2010

10. INFORMATION ABOUT THE REVISION OF THE GUIDANCE DOCUMENT ON DERMAL ABSORPTION

Mr STEINKELLNER gave a presentation on the on-going work on the revision of the guidance document. The final report from the outsourced work had already been delivered, discussed and endorsed by the Steering Committee. It has also been discussed by the members of the Toxicology of Pesticides WG. The report also contained a revised draft guidance document. Its structure differs significantly from the current guidance document. A new hierarchy of data was introduced. New default values for dermal absorption in the absence of data are proposed. Extensive guidance on tape stripping was introduced together with recommendations for the use of skin tissue and statistical evaluations. In particular new flow charts will facilitate decision making in the assessment of dermal absorption. It was also agreed to invite an additional ad-hoc expert. Although the maximum timeline for the opinion was June 2011 the planned date for adopting the opinion (after a public consultation) may be brought forward to the end of 2010.

11. MISCELLANEOUS:

Ms NIENSTEDT updated the Panel on the procurement signed December 2009 about the database compilation of study endpoints in Tier 1 pesticide ecotoxicology studies. The contactor has started work.

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

  The Chair gave an overview on the different WGs (Genotoxicity, nanoparticles, etc). At the next SC in early February, Ms DUNIER-THOMANN will make a presentation on Endocrine Disruptor issues in the PPR Unit and on-going work on cumulative risk assessment.

- **Discussion of the list of new requests for Guidance Documents** to be prepared by the PPR Panel submitted by MS via the Pesticide Steering Committee and on the Working Document DG SANCO.

  The Secretariat presented a summary of the requests submitted by MSs to develop Guidance Documents with respective proposed actions to be discussed by the Pesticide Steering Committee on 17 February. Panel Members were given 3 days for commenting and proposing eventual amendments on the proposed actions.

- **ECPA Comments on the triazole opinion**

  A letter from ECPA commenting the triazole opinion published in September 2009 was forwarded to the Panel. The Panel agreed to reply to the letter, with a copy to the Commission, acknowledging the comments made and explaining in general terms which issues are of relevance for Decision Makers or already covered by ongoing or planned activities of the Panel.

The next Plenary meeting will take place on **24-25 March 2010** in Parma, starting at **14h00** on 24 March.