

**38TH PLENARY MEETING OF THE SCIENTIFIC PANEL ON
PLANT PROTECTION PRODUCTS AND THEIR RESIDUES**

HELD IN PARMA ON 18-19 JUNE 2009

(ADOPTED BY WRITTEN PROCEDURE ON 10 JULY 2009)

#	AGENDA
#	Items
1.	Adoption of the agenda, apologies for absence, declarations of interest
2.	Adoption of the opinions reviewing former opinions on the revision of Annexes II and III
3.	Adoption of the opinion on the risk assessment for cumulative exposure of triazoles
4.	Feedback from the IRIS Workshop (JRC Ispra) and on the updating of the Guidance Document on persistence in soil
5.	Information on the development of the new Guidance Document for pesticide exposure assessment for workers, operators, bystanders and residents- Public consultation
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 guidance document on the probabilistic methodologies for modelling dietary exposure to pesticide residues for public consultation
8.	Feedback from the Joint WG on Guidance Document birds & mammals and on the revision of the Guidance Documents aquatic and terrestrial ecotoxicology
9.	Information on the development of the new Guidance Document on emission from protected crop systems (greenhouses and cultivations grown under cover)-Workshop announcement
10.	<p>Miscellaneous</p> <ul style="list-style-type: none">• Feed-back from the Scientific Committee and its Working Groups• New PPR panel inaugural meeting

PARTICIPANTS

Members of the PPR Panel

Mr. D. BARCELO-CUILLERES, Mr. J. BOESTEN, Mr. A. BOOBIS, Ms. C. BOLOGNESI, Mr. A. BUCHERT, Mr. E. CAPRI, Mr. D. COGGON, Mr. A. HARDY (Chairman), Mr. A. HART, Mr. R. LUTTIK, Mr. O. MEYER, Ms. S. MICHAELIDOU-CANNA, Mr. M. MONTFORTS, Mr. A. MORETTO, Mr. M. MÜLLER, Ms. B. OSSENDORP, Mr. W. STEURBAUT, Ms. M. TASHEVA, Ms C. VLEMINCKX.

European Commission

Ms. F. ARENA

Apologies

Mr. H. KÖPP, Mr. M. LIESS

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, Mr. H. STEINKELLNER, Ms. G. BOSCHETTO, Ms. A. DI BIASIO, Ms. A. PASQUIN, Ms. J. RICKETTS.

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

The agenda was adopted without changes; apologies were received from two Panel Members and the representative from the Commission DG SANCO O3. There were no new declarations of interest.

2. ADOPTION OF THE OPINIONS REVIEWING FORMER OPINIONS ON THE REVISION OF ANNEXES II AND III

The PPR Panel has reviewed their opinions on Annexes II & III, issued in 2006 and 2007, to make sure that the data requirements for active substances and plant protection products are up to date at the time of their final revision by the Commission and adoption under the new Regulation.

The PPR Panel discussed the six draft opinions on Annexes II and III, included some final changes and adopted them unanimously. The chair thanked the rapporteurs and the working groups and asked the EFSA secretariat to do the respective editorial checks and make a crosscheck for those chapters/paragraphs that should appear in several opinions (e.g. endocrine disruption, nanomaterials etc.). The 6 opinions should be published in July 2009.

3. ADOPTION OF THE OPINION ON THE RISK ASSESSMENT FOR CUMULATIVE EXPOSURE OF TRIAZOLES

The draft opinion, as amended during the last joint meeting of the Toxicology and Residues WGs was presented by one of the rapporteurs. All parts of the draft opinion were carefully discussed with particular emphasis on the summary and chapters 6 and 7 as they contain essential lessons derived from the exercise and PPR Panel recommendations.

The PPR Panel agreed on the inclusion of some additional changes and adopted the draft opinion unanimously. The rapporteur will update the document in accordance with the agreements reached during the Plenary meeting and the final draft will be circulated to Panel members. The chair thanked the rapporteurs and the working groups and asked the EFSA secretariat to do the last editorial checks. The opinion will be published in August.

4. FEEDBACK FROM THE IRIS WORKSHOP (JRC ISPRA) AND ON THE UPDATING OF THE GUIDANCE DOCUMENT ON PERSISTENCE IN SOIL

The Chair of the Fate WG informed the Panel about the status of the work. The WG met on 11-12th June and part of the WG will meet again on 30th June. A number of opinions for the guidance are scheduled for adoption by the end of 2009 and in the first half of 2010.

The PPR secretariat updated the Panel on the stakeholder workshop “*improved realism in soil risk assessment*” (IRIS) held on 12-14th May 2009 at JRC (IES - Ispra). The workshop was a success and total of 85 participants, with a good balance from MSs, industry, consultancies and academia, were present. A stakeholder report is planned for publication on the EFSA website by mid 2009.

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

The rapporteur presented the draft opinion, to which the draft guidance document is annexed. He introduced the different chapters pointing out important aspects and the changes made to the previous draft version.

Whereas to date, potential risks to residents have been considered as part of the risk assessment for bystanders, a separate risk assessment for residents was now proposed. Variability in exposures within and between subjects was considered. Different percentiles for chronic and acute exposure estimates (75th and 95th respectively) were proposed. Extensive tables, listing proposed standard models and data sets for the different operator exposure scenarios, are provided in the opinion, which, however, still needs some amendment. Comprehensive guidance for the use of default values

for work rates, transfer coefficients, spray drift, and penetration percentages when using personal protective equipment, are also given.

The concept of an Acute Acceptable Operator Exposure Level (AAOEL) has also been introduced. As a consequence, if the recommendations of the draft opinion are retained and accepted, the current Guidance document on AOEL settings will need to be updated. This will be noted, together with other suggestions for further research in the Recommendations section.

It was noted that the current directive did not cover risk assessments for residents explicitly. It was also noted that aggregate exposure was not addressed in the present draft since, at the moment, no suitable methods have been developed.

The rapporteur will circulate an amended draft by July. The Panel agreed that the draft should be made available for public consultation on the EFSA website in August.

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

The PPR secretariat informed the Panel that the 3 outsourced activities were ongoing according to the timeframe presented during the last plenary meeting.

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

The rapporteur informed the PPR Panel about the last WG meeting. Significant progress has been made in the technical chapters of the draft guidance document and the experience from the triazole exercise will be very valuable. Some tasks were re-allocated and a new meeting of the WG is planned in early September. A draft guidance document ready for public consultation should be proposed to the PPR Panel in October.

8. FEEDBACK FROM THE JOINT WG ON GUIDANCE DOCUMENT BIRDS & MAMMALS AND ON THE REVISION OF THE GUIDANCE DOCUMENTS AQUATIC AND TERRESTRIAL ECOTOXICOLOGY

- Guidance Document birds & mammals

The EFSA Secretariat reported back from the latest meeting of the Joint WG on Guidance Document birds & mammals that took place on 12th May. The discussions focussed on the geomean approach. Some MSs support this approach but others are not in favour or are still undecided. If the MS present in the Joint WG are not able to reach a consensus then the Commission will have to decide. Furthermore, the Joint WG would like to know from the PPR Panel if they could give more guidance with

regard to the use of the geomean approach and the NOEC. The UK has suggested a short GD with an introduction, the key steps and equations, guidance on how to deal with the outcomes, and a reference to the Panel Opinion for higher tier assessment on the basis of “allowing” only a certain percentage of pesticides to fail the 1st tier. The WG members are currently commenting on this document. One more meeting will take place on 8th July 2009 and the final Guidance Document should be published by the end of 2009, after MS “take note” at the DG SANCO Standing Committee in October 2009.

- GDs aquatic and terrestrial ecotoxicology

The WG on Ecotoxicological Effects in charge of these two GDs had its 3rd meeting on 26-27th May 2009. The meeting focused on the final discussions regarding the Annex II & III opinion: Ecotoxicological studies, as well as on the tiered approach and the protection goals. A procedure on how to continue the work on the protection goals was developed. The protection goals document and the tiered approach will be combined into one document as an opinion. The document should include an analysis of legislation requirements, a proposal of the tiered approach, acceptability criteria, and the outcome for each group of organisms.

The document should be ready for a RM stakeholder consultation back to back with the SCFCA in Jan 2010 and later a stakeholder workshop (e.g. in March/April 2010).

The next meeting of the WG Ecotoxicological Effects will take place on 30th June-2nd July 2009 and will focus on protection goals. Further items will be discussed, such as RA for rice and amphibians.

9. INFORMATION ON THE DEVELOPMENT OF THE NEW GUIDANCE DOCUMENT ON EMISSION FROM PROTECTED CROP SYSTEMS (GREENHOUSES AND CULTIVATIONS GROWN UNDER COVER)-WORKSHOP ANNOUNCEMENT

The WG on emissions from protected crops met on 11-12th June 2009. The meeting focused on the current status of the data collection which will be finished by the end of June. Reports on the outcome are planned to be available in late summer. Furthermore, the WG developed a plan for preparing the output in the next half year. The WG also discussed the design of the PROTEA workshop, which will be organised by EFSA in Parma on 17-19th November 2009. Information on the workshop has been published on the EFSA website:

http://www.efsa.europa.eu/EFSA/efsa_locale-1178620753812_1211902525164.htm.

The next meeting of the WG is planned for 10-11th September in Parma.

10. MISCELLANEOUS

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

No time left for this item.

PANEL PLANT PROTECTION PRODUCTS AND THEIR RESIDUES

- **New PPR panel inaugural meeting**

The list of names of the new Panel members (2009-2012) was published on the EFSA website. The first Plenary meeting of the new Panel will take place on **2-3rd July 2009** in Parma, starting at **14h00 on 2nd July at the Grand Hotel de la Ville**.

The election of the Chair and 2 Vice-Chairs will take place on the morning of 3rd July.

- **Feedback from Commission on fate of adopted opinions**

F.ARENA commented a table summarising the fate of the opinions adopted by the Panel since 2006, in particular how the conclusions of the opinions were taken on board in the decision of the Standing Committee.

F.ARENA explained the latest developments regarding the adoption of the new regulation on pesticides in the European Parliament and Council, postponed until the Swedish presidency.

The Chair warmly thanked the Panel members and secretariat for the tremendous work done in the last 3 years and said goodbye to the members who will not be part of the next Panel.