

**37TH PLENARY MEETING OF THE SCIENTIFIC PANEL ON  
PLANT PROTECTION PRODUCTS AND THEIR RESIDUES**

**HELD IN PARMA ON 22-23 APRIL 2009  
(ADOPTED BY WRITTEN PROCEDURE ON 15 MAY 2009)**

#	AGENDA
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 on aquatic and terrestrial ecotoxicology
4.	Discussion on activities regarding endocrine disruptors (DG ENV participation webconference)
5.	Information on the development of the new Guidance Document on emissions from protected crop systems (greenhouses and cultivations grown under cover)
6.	Presentation of draft opinion on the risk assessment for cumulative exposure of triazoles
7.	Presentation of the Guidance Document on the probabilistic methodologies for modelling dietary exposure to pesticide residues 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 development of the new Guidance Document for pesticide exposure assessment for workers, operators, bystanders and residents
10.	Feed back on public consultation on the revision of the dermal absorption Guidance Document
11.	Presentation of the draft Guidance Document on persistence in soil, Ispra Workshop
12.	Discussion on reviewing the opinions of 2006/2007 on Annexes II and III
13.	Miscellaneous: <ul style="list-style-type: none"> <li>• Feed-back from the Scientific Committee and its Working Groups:           <ul style="list-style-type: none"> <li>◦ Discussion on the implementation of the GD Transparency</li> <li>◦ Presentation of the opinion on existing approaches incorporating replacement, reduction and refinement of animal testing: applicability in food and feed risk assessment.</li> </ul> </li> <li>• Presentation of GMO unit regarding environmental risk assessment of genetically modified herbicide tolerant plants and the interplay between Directives 2001/18/EC- 91/414/EEC</li> <li>• FOCUS version control.</li> </ul>

## PARTICIPANTS

### *Members of the PPR Panel*

Mr. D. BARCELO-CUILLERES, Mr. J. BOESTEN, Ms. C. BOLOGNESI, Mr. A. BUCHERT, Mr. E. CAPRI (on 23<sup>rd</sup> April only), Mr. D. COGGON, Mr. A. HARDY (Chairman), Mr. R. LUTTIK, Mr. O. MEYER, Mr. M. MONTFORTS, Mr. A. MORETTO, Mr. W. STEURBAUT, Ms. M. TASHEVA, Ms C. VLEMINCKX.

### *Apologies*

Mr. A. BOOBIS, Mr. A. HART, Mr. H. KÖPP, Mr. M. LIESS, Ms. S. MICHAELIDOU-CANNA, Mr. M. MÜLLER, Ms. B. OSSENDORP.

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.

For item 4: webconference with P. KORYTAR (DG ENV D1).

For item 13: D.MAURICI (SC) and K. L'HEUREUX (GMO).

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

The agenda was adopted without changes; apologies were received from seven Panel Members and the representative from the Commission. There were no new declarations of interest. The Chair welcomed a new secretary in the PPR unit: A. PASQUIN who arrived mid-March.

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

The EFSA Secretariat reported back from the two meetings of the Joint WG on Guidance Document RA Birds & Mammals that took place on 11 March and 2 April, respectively. The WG consists of representatives from six MS, two Panel Members (as scientific experts) and the Commission (also chairing the meeting). The task of this WG is to consider the risk management issues in the Scientific PPR Opinion (EFSA Journal, 2008, 734: 1-181) and finalise the revised GD on RA for birds & mammals on the basis of this opinion.

The first meeting focused on the explanations of task and background, gave the possibility to ask questions and present the views of the MS. A list of issues to discuss

was elaborated and an overall work plan was established. The second meeting concentrated entirely on the discussions regarding reproductive risk assessment and good progress was made. From this second meeting a request was forwarded to the PPR Panel to consider the elaboration of two additional opinions. One would be to review the need for the vole scenario in the GD, addressing specific questions such as which species do voles represent etc. The Panel Members were further asked to consider the elaboration of an opinion regarding clear scientifically-based rules on when to apply the STE approach (covering both birds and mammals). The Panel Members decided to draft terms of reference and discuss them before this Panel comes to an end (June 2009). The related opinions will then be issued by the new Panel, with work probably not starting before September 2009.

The Joint WG was also assured that a software tool for calculations of first tier exposure would be developed. An informal meeting with colleagues from PRAPeR and AMU will take place during the first week of May to check what tools might already be available and what further tools would be needed exactly. On that basis, technical specifications will be drafted and the work could then either be outsourced or taken on board by the AMU unit.

Two more meetings will take place on 12 May and 08 July 2009. All MS will then have the opportunity to carefully read the next draft in summer before the Standing Committee (SCFCAH) will then officially take note of the document in their October 2009 meeting. The Commission will propose an implementation date, which should be included in the document. The GD will finally be published on the EFSA website with a link to the Commission website.

### **3. INFORMATION REGARDING THE REVISION OF THE GDs ON AQUATIC AND TERRESTRIAL ECOTOXICOLOGY**

The WG on Ecotoxicological Effects is in charge of these two GDs and had its 2<sup>nd</sup> meeting on 25-26 March 2009. A presentation on the Thematic Strategy on the Sustainable Use of Pesticides was given by A. C. COTILLON of DG ENV and is available on the Extranet. The WG briefly discussed the potential review of the opinions on Annexes II & III that were issued in 2006 and 2007. More detailed discussion on this topic can be found under agenda item 12 of these minutes. Regarding the protection goals, it became clear that there is a need to discuss the involvement of risk managers at an earlier stage, e.g. via a hearing meeting in 2009. This is one of the lessons learnt from the GD on RA for birds and mammals. The WG is aiming at issuing a separate opinion on the protection goals. A presentation on the soil ecoregions concept, under development in the Ecoregion WG, was given. EFSA will place the latest version of the related presentation on the Extranet. The WG Ecotoxicological Effects is also in charge of the Environmental Risk Assessment Validation Project (former TER-project) and the kick-off meeting on 12 March 2009 discussed the objectives of the project. A call for outsourcing needs to be launched soon. The WG very generally discussed the topic of endocrine disruptors. Further details are discussed under agenda item 4 of this Plenary meeting. The next meeting

of the WG Ecotoxicological effects will take place on 26-27 May 2009 and will focus on protection goals, Annex II & III, Communication strategy and involvement of stakeholders, identification of potential outsourcing (2009/2010) and the identification of further possible opinions.

#### **4. DISCUSSION ON ACTIVITIES REGARDING ENDOCRINE DISRUPTORS**

The future new Regulation of the European Parliament and of the Council concerning placing plant protection products on the market and repealing Council Directives 79/117/EEC and 91/414/EEC states that the *“Com shall present (...) a draft of the measures concerning specific scientific criteria for the determination of endocrine disrupting properties (...).”*

The PPR Secretariat contacted the Commission to discuss if they are expecting any cooperation regarding this task. P. KORYTAR from the Commission (DG ENV, Unit D1: Chemicals) participated *via* web conference and presented the Community Strategy on Endocrine Disrupters. The presentation will be made available on the Extranet.

DG ENV is currently preparing a work plan to co-ordinate, intensify and further develop the Commission's activities on endocrine disruptors including their identification. The plan should include timelines and suggestions on how to involve the relevant agencies and Commission services. In addition to the newly adopted PPP Regulation, the plan should also address issues arising from other legislation (such as REACH or the Water Framework Directive) and other Commission commitments (such as those contained in the Community Strategy for Endocrine Disrupters). The Commission expects to have a draft plan ready for consultation by mid-July 2009.

The Panel Members discussed some specific topics like related OECD guidelines, how to define the result of a reproductive test as based on an endocrine disruptive mechanism, hazard-based risk management versus risk-based assessment and the different mechanisms of endocrine disruption leading to different effects. It was also mentioned that testing of endocrine disruption would make sense under the REACH regulation but not under the new PPP regulation.

The chair asked the Commission whether or not they are looking for guidance from the PPR Panel regarding criteria for endocrine disruptors. The Commission is currently preparing contract(s) to go through all of the more than 80 project reports that have been funded via the Community Framework Programme for R & D within the FP4-7. The Commission's intention is to then ask the PPR Panel's opinion on the resulting reports. This should probably be a task for 2011.

The Panel Members agreed to discuss this topic in more depth within the Toxicology WG and report back to the Commission and keep the Scientific Committee informed.

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

The Chair 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). The WG met on 5–6th February and will meet again on the 23–24th April.

The PPR secretariat presented the status of the data-collection. Two procurements for evaluation of emission routes to environmental compartments have been completed and are available on the EFSA web-page. The data-collection on structures of protected crops systems in EU is ongoing partly through two procurements and partly through the EFSA AMU unit. Three Steering Group meetings have been held since the start of the project in January. The data-collection is expected to be reported by mid-2009.

The draft project plan on how to develop the new Guidance Document was published for comments in an open web-consultation from 20 October to 15 December 2008. Comments have been collected and the outcome of the public consultation will be published on the EFSA website.

**6. PRESENTATION OF DRAFT OPINION ON THE RISK ASSESSMENT FOR CUMULATIVE EXPOSURE OF TRIAZOLES**

The rapporteur presented the state of activities regarding the drafting of the opinion. The Panel agreed on the appointment of a third rapporteur whose task is to ensure coordination and structuring of the opinion. Two chapters of the opinion (evaluation of the methodologies, recommendations and conclusions) are still under development. The other parts of the opinion are close to finalisation. The amended probabilistic report has been made available by the contractor and was accepted by EFSA.

The main outcomes of the last joint meeting of the Toxicology and Residues Working Groups and the tasks still to be performed were listed.

It was pointed out that the Adjusted Hazard Index (aHI) and the NOAEL-based RPF approaches may lead to the same results in case the same Assessment Factors are applied to pesticides forming the Common Assessment Group. In such a case, it is debatable whether the NOAEL-based RPF methodology can be considered as a refinement of the aHI methodology. It was also mentioned that the exercise was based on Reference Values, which are no longer valid as a lot of triazole compounds have been evaluated during the last months in the framework of Directive 91/414/EC.

Panel Members were invited to make written comments regarding the current draft opinion (adoption is foreseen on 18 June 2009).

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

The secretariat informed the Panel that due to the heavy workload related to the cumulative risk assessment of triazole pesticides, no progress could be made by experts on the drafting of the guidance document on the use of probabilistic methodologies for dietary exposure assessment of pesticide residues. It might therefore be necessary to adjust the timetable regarding delivery of this opinion.

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

The Panel Members were informed by the secretariat on the progress of the outsourced activities regarding the Threshold of Toxicological Concern (TTC), the QSAR analysis and the impact of metabolism on the toxicological properties of pesticides. All these projects are currently ongoing and a preliminary report regarding the TTC project has been submitted and accepted.

In addition, the Permanent Working Group met for the first time on 31st March. It was decided to create a special space within the Extranet for exchange of information on the active substances selected for case studies in the different projects.

**9. INFORMATION ON THE DEVELOPMENT OF THE NEW GUIDANCE DOCUMENT FOR PESTICIDE EXPOSURE ASSESSMENT FOR WORKERS, OPERATORS, BYSTANDERS AND RESIDENTS**

The rapporteur gave a brief overview about the new version of the draft opinion. The Panel was informed about current progress and that most of the opinion has been drafted. A part that still requires some effort was the proposals for the standard data sets. One major change discussed was the use of 95th percentile instead of 97.5th percentile for the acute risk assessment.

The data sets for some operator scenarios were indeed very lean. Industry holds further data on workers that is not publicly available.

The Panel was informed about the foreseen timetable: an almost complete draft version will be circulated by the end of May. The Panel will then have the possibility to discuss the next version in June. Launch of a public consultation about the text is foreseen for August. The text will then be further revised in October, based on the outcome of the public consultation. The aim is to adopt the opinion in December 2009.

The secretariat informed the Panel that permission has now been received for publishing the final report from the Art. 36 call. After some administrative steps the report will be posted on the EFSA Website.

## **10. FEEDBACK ON THE PUBLIC CONSULTATION ON THE REVISION OF THE DERMAL ABSORPTION GUIDANCE DOCUMENT**

The Secretariat informed the Panel that the report on the outcome of the public consultation had been published on the EFSA website on 25th March. A procurement procedure for outsourcing a literature review, analysis of the current guidance document and drafting a text proposal for the revised guidance document was launched on 20th April. Delivery of the final report is scheduled for the end of January 2010 (7 months after contract signature). The revised guidance document is expected to be delivered within 18 months after that report.

## **11. PRESENTATION OF THE GUIDANCE DOCUMENT ON PERSISTENCE IN SOIL, ISPRA WORKSHOP**

The Chairperson of the Fate WG informed the Panel about the status of the work. The WG met on 18 -19th March and 21 -22nd April.

The PPR secretariat updated the Panel on the preparation of the stakeholder workshop *“Improved realism in soil risk assessment”* (IRIS). The workshop will be held on 12 to 14 May 2009 at JRC (IES) in Ispra. Approximately 85 participants are foreseen including participants from MSs, academia and industry. The programme and the presentations at the workshop will be available for the participants before the workshop.

## **12. DISCUSSION ON REVIEWING THE OPINIONS OF 2006/2007 ON ANNEXES II AND III**

The Panel proposed to revisit (self task) the review of the PPR opinions on Annexes II & III adopted in 2006/2007 because the Annexes II and III to Council Directive 91/414/EEC have not been finally amended yet by the Commission. The aim is to make sure that the data requirements for the risk assessment of active substances and plant protection products are up to date. Moreover a new Regulation is still in discussion in European Parliament and Council and should be adopted in 2009.

The PPR Panel members discussed and agreed the draft Terms of Reference with background which will be sent by the Chair to the EFSA's Executive Director for agreement.

The time line is very tight and the opinions or statements have to be adopted at the last Panel Plenary meeting in June and published before the summer break.

At the request of Commission, the Panel also discussed the relevance of adding some indication on the current data requirements in risk assessment for nanopesticides. The Panel agreed to prepare a short text but concluded that a detailed assessment will require a separate mandate from the Commission.

### 13. MISCELLANEOUS

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

The Chairman briefly informed the Panel members on the outcome of the last Scientific Committee meeting held on 7-8 April 2009.

- **Discussion on the implementation of the GD Transparency**

D. MAURICI detailed the opinion on Transparency in risk assessment recently adopted by the SC. T. HARDY was representing the PPR Panel in that WG. It was suggested that the new Panels will discuss the implementation of the opinion in their work.

- **Presentation of the opinion on existing approaches incorporating replacement, reduction and refinement of animal testing: applicability in food and feed risk assessment.**

D. MAURICI also presented the opinion adopted by the SC and circulated to Panels. O. MEYER was representing the Panel in that WG.

The implementation should be promoted in all GDs produced by EFSA.

- **Presentation of GMO unit regarding environmental risk assessment of genetically modified herbicide tolerant plants and the interplay between Directives 2001/18/EC- 91/414/EEC**

K. L'HEUREUX presented the current situation regarding the future adoption of the opinion on GMO herbicide tolerant maize NK603; the PPR Panel was asked by the GMO Panel to be consulted for advice regarding the environmental risk linked to use of this herbicide (possible impact on non target organisms). A fruitful exchange of information with Panel members followed.

- **FOCUS version control.** At the SCFCAD meeting at the end of 2008 it was decided to transfer the FOCUS version control from FOCUS to EFSA. The PPR secretariat provided an out-line on how the version control will be organised at EFSA. The version control of environmental exposure models and guidance is essential to support reproducible and reliable risk assessments of plant protection products.

The next **PPR Plenary meeting** will take place on **18-19 June 2009** in Parma, starting at **9h00 on 18th June**.