

## PANEL PLANT PROTECTION PRODUCTS AND THEIR RESIDUES

### 36<sup>TH</sup> PLENARY MEETING OF THE SCIENTIFIC PANEL ON PLANT PROTECTION PRODUCTS AND THEIR RESIDUES

**HELD IN PARMA ON 4-5<sup>TH</sup> FEBRUARY 2009**

**(ADOPTED BY WRITTEN PROCEDURE ON 5 MARCH 2009)**

#	AGENDA
1.	Adoption of the agenda, apologies for absence, declarations of interest
2.	Information on the development of the new Guidance Document for pesticide exposure assessment for workers, operators, bystanders and residents
3.	Presentation of the draft Guidance Document on persistence in soil
4.	Information on the development of the new Guidance Document on emission from protected crop systems (greenhouses and cultivations grown under cover)
5.	Presentation of draft opinion on the risk assessment for cumulative exposure of triazoles
6.	Feed back on public consultation on the revision of the dermal absorption Guidance Document
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 dietary risk assessment Guidance Document
9.	Feed back on public consultation on the revision of the aquatic and terrestrial ecotoxicology Guidance Documents
10.	Miscellaneous: - Renewal of Panel and EFSA policy on experts - Feed-back from the Scientific Committee and its Working Groups: <ul style="list-style-type: none"> <li>• Benchmark Dose Approach in Risk Assessment</li> <li>• Discussion on the implementation of the GD Transparency</li> </ul> - Cooperation PPR Unit and DG SANCO in the area of pesticide residues - Debriefing on second reading in EP-vote 13th January - Other items: debriefing Pesticides Steering Committee (PRAPeR unit)

## PARTICIPANTS

### *Members of the PPR Panel*

Mr. D. BARCELO-CULLERES, 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. H. KÖPP, Mr. R. LUTTIK, Mr. O. MEYER, Mr. M. MONTFORTS, Mr. A. MORETTO, Mr. M. MÜLLER, Ms. B. OSSENDORP, Mr. W. STEURBAUT, Ms. M. TASHEVA, Ms C. VLEMINCKX.

### *Apologies*

Mr. M. LIESS, Ms. S. MICHAELIDOU-CANNA

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, H. STEINKELLNER, Ms.G. BOSCHETTO, Ms. A. DI BIASIO, Ms. RICKETTS.

For item 10 only: R. MAIJALA (Director Risk Assessment), B.BOTTEX (SC) and C. WOLFF (Legal and Policy affairs).

## **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. There were no new declarations of interest.

## **2. 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 of the structure of the Guidance Document (GD) and of the related opinion. The introduction will refer to the report regarding the Art. 36 grant. The Panel was informed about the scope of the opinion and the definitions of the exposure groups were discussed. A brief outline of the current legal requirements will be included. A section will be prepared on current approaches, the validity of current methods and the problems and uncertainties associated with current approaches. Development of the new GD will start with proposals for standard models and data sets. Draft wording for a GD will be presented in an Annex to the opinion with options for risk managers to make modifications if they wish to change levels of precaution. Critical issues are whether there should be separate acute risk assessments, choice of percentiles from sample measurements of exposure, and approaches to small data sets. The Panel discussed its position on each of these topics.

The Panel was informed about the state of the publication of the final report coming from the Art. 36 call. The timeline and the composition of the WG were agreed.

### **3. PRESENTATION OF THE DRAFT GUIDANCE DOCUMENT ON PERSISTENCE IN SOIL**

The chair of the WG reported on the progress and gave an update on the outcome of the last meeting held in Parma on 3/4 February 2009. A report on the response of the WG to the comments of the public consultation was published in January on the EFSA webpage. A stakeholder workshop planned for 12/14 May will be held at JRC in Ispra (VA), Italy. The programme is currently under development and will comprise an initial information session, one day of work in break-out groups to discuss specific topics, and a closing session summarizing the outcome of the break-out groups and a final round of discussions. In the February WG meeting, the WG had a general discussion on the level of detail to be included in the scenario selection and the development. The out-line for the scenario selection road-map will be continued at the next meeting on 18/19 March 2009 in Amsterdam.

### **4. INFORMATION ON THE DEVELOPMENT OF THE NEW GUIDANCE DOCUMENT ON EMISSION FROM PROTECTED CROP SYSTEMS (GREENHOUSES AND CULTIVATIONS GROWN UNDER COVER)**

The WG on emissions from protected crop systems received two final position papers: “Emissions by aerial routes from protected crop systems (greenhouses and crops grown under cover)” and “Emissions by ‘other routes than air’ from protected crops systems”, which were outsourced under an EFSA negotiated procedure. Both reports will be published on the EFSA website. Furthermore, data collection has started for the assessment of distribution of protected crop systems in the EU *via* a negotiated procedure. Two contractors were selected for the Southern and Eastern part of Europe. No offer was received for the North-Western part; consequently EFSA’s AMU unit will support the PPR Panel for this task. A first steering group meeting took place in Parma on 23<sup>rd</sup> January and the procedure for harmonized data collection in all three zones was defined. Data collection is supposed to be completed by June 2009. The public consultation on the project plan for the development of the new GD, which ended in December 2008, yielded 25 comments which were all generally supportive of the ongoing activities. Comments will be reviewed in the next meeting of the WG in Parma on 5/6 February. As also suggested in the Public Consultation comments, the WG decided to organize a workshop in autumn 2009 for further feedback from stakeholders who will be invited to participate.

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

The rapporteur presented the state of work regarding the draft opinion and the latest progress made by the WGs. The activities since the last plenary meeting included one joint meeting of the Toxicology and Residues WGs in December and 2 meetings of the Residues WG in January and February. Most of the deterministic calculations have been conducted, except for some scenarios regarding French population where consumption data are lacking. Several structural changes have been agreed in order to

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improve the fluency of the document. This implies rearrangement of sections already drafted. A major part of the opinion, including discussion of the results, evaluation of the methodologies, lessons learnt and possible recommendations, still needs to be drafted.

An update regarding the contractual services requested for probabilistic calculation was also given.

The detailed timeline for the activities was discussed in order to ensure adoption during the mandate of the current Panel.

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

EFSA reported that in total 77 comments had been received within the frame of the public consultation procedure that lasted for two months and closed on 15<sup>th</sup> January. Many of these comments addressed more than one single issue. Some of the main issues were requests for updates of the text and references, application of tape stripping, application of default values, defining end of absorption in *in vivo* experiments, harmonisation of study design and interpretation of poorly designed studies. The public consultation guaranteed involvement of stakeholders at an early stage of the work and helped identify important issues to be addressed for the revision. The outcome of the public consultation will also be an important background document for the contractor selected for the negotiated procedure: work should start at the beginning of April, the final report should be available six months later – this will be the starting point for drafting the opinion and the revised guidance document (forecast timeframe: 18 months).

EFSA will now analyse and process the comments received in the form of a report that will be circulated to the WG for discussion and endorsement at the next WG meeting in April. The report should be published on the EFSA website by the end of April.

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

Work on this guidance document is not sufficiently advanced to launch a public consultation at this stage. The Rapporteur presented the outcome of the working group meetings preceding the Plenary. In particular a new structure was proposed for the document as well as a new way of presenting outputs of modelling based on the incidence in population of cases reaching different Margins of Exposures (MoEs). This implies the necessity of considering how to connect this approach with the levels of protection targeted at Risk Management level. Considering the need for in-depth consideration of the draft guidance document by the Panel and the procedural requirements of public consultation, it was proposed to postpone the public consultation to the summer period.

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

The Panel was informed that an Article 36 grant contract has been signed for a project aimed at examining the impact of metabolic processes on the toxicological properties of pesticides. Moreover another contract (Service Level Agreement) will be signed soon with JRC on the applicability of QSAR analysis in the evaluation of the toxicological relevance of pesticide metabolites. In order to improve integration of the 3 outsourced activities, the Panel agreed on the composition of a permanent WG.

### **9. FEED BACK ON PUBLIC CONSULTATION ON THE REVISION OF THE AQUATIC AND TERRESTRIAL ECOTOXICOLOGY GUIDANCE DOCUMENTS**

Following two preparatory meetings with Panel members, PRAPeR and PPR Unit colleagues in September and November 2008, the official kick-off meeting regarding the revision of the Guidance Documents “Aquatic Ecotoxicology” and “Terrestrial Ecotoxicology” took place on 27/28 January 2009 in Parma. In particular, the meeting was aimed at discussing the outcome of the surveys carried out in autumn 2008 (questionnaire to risk managers, web public consultation), protection goals in different legislative frameworks and scientific principles that need to be taken into account. EFSA’s Risk Assessment Director stated that industry representatives could be involved via technical hearings but that cooperation in drafting text is not possible. The next meeting will take place on 25/26 March in Parma.

### **10. MISCELLANEOUS**

- **Renewal of Panel and EFSA policy on experts**

- R. MAIJALA explained the timing of the ongoing evaluation of applications for the renewal of the Panel; the final list will be approved by the Management Board at the end of March and should be published in May.

- She then explained in detail the EFSA policy regarding potential participation of experts from industry in the WGs. Those particular experts could be invited to a limited number of technical meetings as “hearing experts”. They are invited to present their position, data and answer questions but will not participate in the drafting of the opinion and will not be a member of the WG. In the pesticide sector, the importance of involving industry all along the development of EU Guidance Documents – and not only in public consultation and Workshops - was highlighted by members of the Panel.

- Panel members reported that some external experts had complained about not being properly acknowledged for their contributions and intellectual efforts, especially for long term work such as Guidance Documents, as their names appear only after the summary in the opinion. A much better visibility is requested as e.g.

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for authors in peer review journals. R. MAIJALA explained EFSA is still working on better scientific recognition of the EFSA journal.

- The Panel members would appreciate an annual feedback from DG SANCO E3 on the use of the EFSA opinions in the final decision regarding inclusion/non-inclusion of an active substance in Annex I of the Directive 91/414/EEC (e.g. deltamethrin, recently adopted).

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

The Chairman briefly informed the Panel members on the outcome of the last Scientific Committee meeting held in December 2008, in particular on the WG Transparency. The opinion should be adopted in June 2009 after a public consultation and the new Panels will discuss how they could implement the opinion in their area.

-O. MEYER explained that the draft on existing approaches of animal testing is quite advanced and should be circulated to Panels by the next Plenary.

- B. BOTTEX (SC) explained the aim of the consultation of Panels (*via* a questionnaire) on the draft opinion on the use of Benchmark Dose Approach in Risk Assessment. Written comments are requested by 15<sup>th</sup> March to B. BOTTEX with a copy to the PPR Secretariat.

- **Cooperation PPR Unit and DG SANCO in the area of pesticide residues**

L. MOHIMONT gave a feedback on a recent discussion with Commission colleagues of DG SANCO E3 in charge of the Residues Legislation.

The aim was to update and inform the Commission on the ongoing activities regarding guidance documents and to present the view of EFSA and its WGs on Toxicology and Residues about future cooperation between EFSA (PPR Panel), the Commission and Member States in order to meet the objectives of Regulation 396/2005 regarding Cumulative Risk Assessment. In this context it was felt very useful to have a follow-up on Cumulative Risk Assessment after adoption of the opinion on triazole fungicides.

- **Debriefing on second reading in EP-vote 13th January**

C. WOLFF (Legal and Policy affairs) gave an overview on the latest developments in European Parliament on the proposal for a Regulation concerning the placing of plant protection products on the market, in particular on the recent vote in European Parliament. The latest texts will be put on the EFSA Extranet as requested.

- **Other items: debriefing Pesticides Steering Committee (PRAPeR unit)**

The second Pesticide Steering Committee (PSC) meeting was held on 2/4 February in Parma, chaired by the PRAPeR's Head of Unit.

M. DUNIER-THOMANN presented the work of the PPR Panel regarding development and updating of Guidance Documents.

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The list of all existing Guidance Documents in Annex IV of the “Efficiency report” published in summer 2008 should be completed and updated with regard to e.g. responsibilities.

PSC wants to review the priorities every year regarding the GDs for revision and development, therefore the Member States should present a priority list of new requests to the Panel, to be considered for the workplan 2009-2013, at the next meeting of the PSC in April. The limited resources available in the Panel and the PPR unit, taking into account the current programme, were highlighted.

The next **PPR Plenary meeting** will take place on **22-23<sup>rd</sup> April 2009** in Parma, starting at 14h00 on 22<sup>nd</sup> April.