

**PANEL ON PLANT PROTECTION PRODUCTS AND THEIR RESIDUES**

**39<sup>th</sup> INAUGURAL PLENARY MEETING OF THE SCIENTIFIC PANEL ON  
PLANT PROTECTION PRODUCTS AND THEIR RESIDUES**

**HELD IN PARMA ON 2-3 JULY 2009**

**(ADOPTED BY WRITTEN PROCEDURE ON 18<sup>TH</sup> AUGUST 2009)**

**Meeting date: 2nd July 2009**                      **Afternoon common session (PPR-NDA-AHAW Panels)**  
**Time: 14h00 – 18h00**  
**Place: Grand Hotel de la Ville, Trovatore Meeting Room, Largo P.Calamandrei, Parma**

1.	Welcome and opening of the meeting, general introduction to EFSA, with the participation of Diana Banati, Chair of the Management Board.	Catherine Geslain Lanéelle
2.	Presentation of EFSA	
2.1	Introduction of the Risk Assessment Directorate and the scientific work of EFSA	Riitta Liisa Maijala
2.2	Scientific Committee and Advisory Forum	Djien Liem
2.3	Scientific Cooperation and Assistance Directorate	Hubert Deluyker
2.4	Communication strategy of EFSA	Anne Laure Gassin / Steve Pagani
2.5	Legal aspects/declarations of interest	Dirk Detken
2.6	Declarations of Interest: Information Technology Tool	Ernesto Guisado Ferrer
2.7	Financial aspects	Mari Varho

**Meeting date: 3rd July 2009**                      **Morning session (PPR Panel only)**  
**Time: 08h30 – 14h00**  
**Place: EFSA Meeting Room DUS D 00/002, Largo N.Palli 5/A, Parma**

#	Agenda
1.	Round table presentation of Panel Members and of Secretariat
2.	Election of Panel Chair and Vice Chairs
3.	Adoption of the agenda, apologies for absence, Declarations of Interest
4.	PPR Panel Work Programme for 2009-2012 <ul style="list-style-type: none"> <li>- Opinions</li> <li>- Guidance Documents</li> <li>- Meeting dates</li> </ul>
5.	Presentations on Guidance Documents (GDs) under revision and/or elaboration: <ul style="list-style-type: none"> <li>5.1 Revision of the GD on persistence in soil</li> <li>5.2 Development of the new GD on emissions from protected crop systems (greenhouses and cultivations grown under cover)</li> <li>5.3 Revision of the GDs on aquatic and terrestrial ecotoxicology</li> <li>5.4 Development of the new GD for pesticide exposure assessment for workers, operators, bystanders and residents</li> <li>5.5 Development of the new GD on the probabilistic methodologies for modelling dietary exposure to pesticide residues</li> <li>5.6 Development of the new GD on evaluation of the toxicological relevance of metabolites and degradates of pesticide active substances for dietary risk assessment</li> <li>5.7 Revision of the GD on dermal absorption</li> <li>5.8 Revision of the GD on risk assessment of birds and mammals</li> </ul>
6.	Miscellaneous. SC opinion on transparency.

## PANEL ON PLANT PROTECTION PRODUCTS AND THEIR RESIDUES

### PARTICIPANTS

#### *Members of the PPR Panel*

Ms. A. ALIX, Mr. J. BOESTEN, Ms. C. BOLOGNESI, Mr. E. CAPRI, Mr. A. HARDY (Chairman), Mr. A. HART, Ms K. HIRSCH-ERNST, Ms. S. HOUGAARD, Mr. R. LUTTIK, Mr. A. MORETTO, Ms. B. OSSENDORP, Ms. A. PETERSEN, Ms. Y. PICO`, Mr. A. SCHAEFFER (3<sup>rd</sup> July only). Mr. P. SOUSA, Mr. W. STEURBAUT, Ms. A. STROMBERG, Ms. M. TASHEVA, Mr. T. VAN DER LINDEN, Ms C. VLEMINCKX.

#### *Apologies*

Mr. J. TARAZONA

#### *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. PASQUIN, Ms. J. RICKETTS.

#### *COMMISSION*

Mr. X. PAVARD (DG SANCO O3)

## Minutes of the 39<sup>th</sup> PPR Panel meeting

### 2<sup>nd</sup> July (PPR-NDA-AHAW Panels)

#### 1. PRESENTATION OF EFSA

An introduction was given by D.BANATI, Chair of the Management Board, and C.GESLAIN-LANEELLE, Executive Director of EFSA. This was followed by a series of general introductory presentations giving an overview of the different departments and their responsibilities within EFSA: 2.1) Introduction to the Risk Assessment Directorate and the scientific work of EFSA; 2.2) Introduction to the Scientific Committee and Advisory Forum; 2.3) Introduction to the Scientific Cooperation and Assistance Directorate; 2.4) Communication strategy of EFSA; 2.5) Legal aspects; 2.6) Declarations of Interest and 2.7) Financial aspects.

### 3<sup>rd</sup> July (PPR Panel)

#### 1. ROUND TABLE PRESENTATION OF PANEL MEMBERS AND OF SECRETARIAT

#### 2. ELECTION OF PANEL CHAIR AND VICE CHAIRS

The Chair was elected with unanimity as T. HARDY was the only candidate.

The first Vice-Chair was elected with the quorum: A. MORETTO

The second first Vice-Chair was elected with the quorum: R. LUTTIK

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## PANEL ON PLANT PROTECTION PRODUCTS AND THEIR RESIDUES

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

The agenda was adopted without changes; apologies were received from one Panel Member who will resign due to his new employment. He will be replaced after the Management Board has approved a new applicant proposed from the reserve list.

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.

### 4. PPR PANEL WORK PROGRAMME FOR 2009-2012

M. DUNIER-THOMANN presented an overview of the current work programme, explained the questions expected from the Commission, listed the Guidance Documents being prepared and the work foreseen for the coming years.

The Pesticide Steering Committee will propose a list of priorities to the PPR unit regarding EU Guidance Documents to be updated/created in early September. The list will be discussed at the next Plenary.

### 5. PRESENTATIONS ON GUIDANCE DOCUMENTS (GDS) UNDER REVISION AND/OR ELABORATION

#### 5.1 Revision of the GD on persistence in soil

The Chair of the Fate WG informed the Panel about the status of the work. The WG met on 11-12<sup>th</sup> June and part of the WG met again on 30<sup>th</sup> June to discuss supplementary soil and weather data from JRC. A number of opinions for the guidance are scheduled for adoption by the end of 2009 and in the first half of 2010. One opinion was adopted in December 2008 (metrics in soil).

The report from the stakeholder workshop "*Improved realism in soil risk assessment*" (IRIS) held on 12-14<sup>th</sup> May 2009 at JRC-IES (Ispra) is planned for publication in July 2009.

#### 5.2 Development of the new GD on emissions from protected crop systems (greenhouses and cultivations grown under cover)

The chairperson of the WG presented the project. The WG on emissions from protected crops met on 11-12<sup>th</sup> June 2009. The meeting focused on the current status of the data collection. The outcome is 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 (Pesticide Emissions from Protected Crop Systems), which will be organised by EFSA in Parma on 17-19<sup>th</sup> November 2009. Information on the workshop has been published on the EFSA website:

[http://www.efsa.europa.eu/EFSA/efsa\\_locale-1178620753812\\_1211902525164.htm](http://www.efsa.europa.eu/EFSA/efsa_locale-1178620753812_1211902525164.htm).

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

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### **5.3 Revision of the GDs on aquatic and terrestrial ecotoxicology**

The chair of the joint WG Ecotoxicological Effects presented the current status of the project. The last meeting of this WG took place immediately before this Plenary Meeting. The meeting was focused on protection goals and general concepts to be applied for the revision of the GDs. The results of these discussions will be a scientific opinion, which should include an analysis of legislation requirements, a proposal of protection goals, a proposal of the tiered approach, acceptability criteria, and specific proposals for each group of organisms. The document should be ready for a RM stakeholder consultation back to back with the SCFCAH in January 2010 and later a stakeholder workshop (e.g. in March/April 2010).

Additionally, the secretariat presented further work which may be required in the area of ecotoxicology in the short and medium term.

### **5.4 Development of the new GD for pesticide exposure assessment for workers, operators, bystanders and residents**

I. SEBESTYEN presented an overview about the activities regarding this mandate.

Considered as a high priority by MS, the PPR Panel received a mandate in 2008 for drafting a GD on exposure assessment for workers, operators, bystanders and residents. First of all, preparatory work for drafting a new GD was outsourced. The final report from this project was delivered in November 2008 and is available on the EFSA webpage. Based on this report, the rapporteur drafted an opinion on the GD to which the draft GD is attached in the form of an annex. At the last Plenary meeting the text of the draft opinion was discussed and it was agreed to publish it for a public consultation in August (closing date: 15<sup>th</sup> September). Adoption of the opinion is planned for December 2009. After that risk management elements in the GD should be discussed between MS and the Commission.

In addition to the above, Istvan Sebestyen informed the Panel about the ongoing call for tender for outsourcing preparatory work for the identification of common assessment groups (CAGs) for cumulative risk assessment of pesticides. The deadline for submission of offers is 15<sup>th</sup> September. The establishment of CAGs is a further step in setting up methodologies for cumulative risk assessment of pesticides (after the general opinion on cumulative risk assessment and the opinion on cumulative risk assessment of triazoles). Furthermore, he noted that the current GDs on setting AOEL and ARfD would have to be reviewed as a consequence of new provisions in the future GD on exposure assessment for workers (work to start in 2010). It is also planned to commence the development of a new GD for the evaluation of ADME studies in 2010.

### **5.5 Development of the new GD on the probabilistic methodologies for modelling dietary exposure to pesticide residues**

The chair of the WG gave an overview of the current status of activities regarding the drafting of the guidance document. The structure of the document has been defined and a draft text is available for some parts. The next meeting of the WG will be held in early September. The timelines of the project include a public consultation which is foreseen during the last 2 months of this year. A complete draft of the GD is therefore expected to be submitted to the Panel during the October plenary.

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### **5.6 Development of the new GD on evaluation of the toxicological relevance of metabolites and degradates of pesticide active substances for dietary risk assessment**

The chair of the WG gave a presentation on the state of work. Three outsourced activities are currently ongoing (Threshold of Toxicological Concern, QSAR, Impact of metabolism on the Toxicological properties of Active Substances). The results of these activities, together with other possible approaches will be used as the basis for a scientific opinion on the toxicological relevance of metabolites. As a third step, a GD will be elaborated.

The current objectives of the WG aim at coordinating the outsourced activities and at defining the overall structure of the opinion and the first steps of work.

### **5.7 Revision of the GD on dermal absorption**

H. STEINKELLNER presented the activities regarding this mandate which was received by the PPR Panel in November 2008. In order to involve stakeholders at an early stage of the work and to get information on parts of the current GD that need an update, a public consultation was launched that was closed on 15<sup>th</sup> January 2009. A report containing all the comments received was published on 25<sup>th</sup> March and is available on the EFSA webpage. In April a call for tender for outsourcing preparatory work was launched (closed 25<sup>th</sup> May) and a contractor has already been selected. The final report from this project will be delivered by beginning of 2010 and be the basis for drafting an opinion on the science behind revising the GD (with the GD attached in form of an annex) which will again be subject to a public consultation. The revised GD will be adopted by mid-2011 at the latest.

### **5.8 Revision of the GD on risk assessment of birds and mammals**

C. FUELL gave an overview on the revision of the GD on risk assessment for birds and mammals focussing in particular on the work of the Joint WG. This WG had been established in order to choose from various options in the related opinion published in July 2008, to decide on risk management issues and what should finally be included in the revised GD. The participants are nominees from six Member States, one observer from JRC, two Panel members as technical and scientific experts, C.FUELL from the Unit Secretariat and one representative from DG SANCO chairing the meeting. The Joint WG has already met three times and will have one final meeting on 8<sup>th</sup> July 2009.

The outcome of the work will be presented to the SCFCAH during their October meeting and the final GD should be published by end 2009.

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### 6. MISCELLANEOUS

- **SC opinion on transparency.**

Due to lack of time left for this item, the Chair asked Panel members to read the Transparency Opinion during the summer for discussion on implementation at the next meeting.

The next Plenary meeting will take place on **9/10 September 2009** in Parma, starting at **14h00** on **9<sup>th</sup> September**.

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