

PANEL ON PLANT PROTECTION PRODUCTS AND THEIR RESIDUES

**44th PLENARY MEETING OF THE SCIENTIFIC PANEL ON
PLANT PROTECTION PRODUCTS AND THEIR RESIDUES
HELD IN PARMA ON 24-25 MARCH 2010**

(ADOPTED BY WRITTEN PROCEDURE ON 3 MAY 2010)

#	Items
1.	Adoption of the agenda, apologies for absence, declarations of interest
2.	Adoption of the first Opinion related to the new Guidance Document on emission from protected crop systems (greenhouses and cultivations grown under cover) and information on the WG's progress
3.	Information on the revision of the Guidance Document on Persistence in Soil
4.	Draft Opinion on protection goals: update on stakeholder and RM consultation
5.	Information on Ecoregions mandate
6.	Information on the identification of pesticides to be included in cumulative assessment groups on the basis of their toxicological profile
7.	Guidance Document on the probabilistic methodologies for modelling dietary exposure to pesticide residues: public consultation
8.	Information on draft Opinion on the evaluation of the toxicological relevance of metabolites and degradates of pesticide active substances for the dietary risk assessment Guidance Document
9.	Information about the revision of the Guidance Document on Dermal Absorption
10.	Discussion of terms of references for an Opinion on the acute dietary intake assessment of pesticide residues in fruit and vegetables: impact of changing variables in the IESTI equations on the level of protection.
11.	<p>Miscellaneous:</p> <ul style="list-style-type: none"> Information on AMU WG on submission of scientific peer-reviewed open literature as requested by Regulation 1107/2009 Feed-back from the Scientific Committee and its Working Groups Feed back from the discussion with MS at the Pesticide Steering Committee 17 February on the list of new requests for Guidance Documents to be prepared by the PPR Panel and on the Working Document DG SANCO EPA request for EFSA/EPA Cooperation on the use of unit-to-unit variability in dietary risk assessment of pesticides residues.

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, Ms. A. PETERSEN, Ms. Y. PICO`, Mr. A. SCHAEFFER, Mr. P. SOUSA, Mr. W. STEURBAUT, Ms. A. STROMBERG, Ms. M. TASHEVA, Mr. T. VAN DER LINDEN, Ms C. VLEMINCKX.

Apologies

Mr. X. PAVARD (DG SANCO O3).

EFSA

Mr. O. MAGRANS (PRAPeR unit) and E. AIASSA (AMU unit) only for Item 11.

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 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.

Ms A.ALIX informed the Panel about her future change of responsibility: she will resign from AFSSA to join the French Ministry of Agriculture (DGAL) on 1 April. According to EFSA's policy regarding conflict of interest, she will shortly send a resignation letter to the EFSA Executive Director. The Chairman thanked her warmly for the efficient work carried out so far in the Panel in the area of Ecotoxicology.

2. ADOPTION OF THE FIRST OPINION RELATED TO THE NEW GUIDANCE DOCUMENT ON EMISSION FROM PROTECTED CROP SYSTEMS (GREENHOUSES AND CULTIVATIONS GROWN UNDER COVER) AND INFORMATION ON THE WG'S PROGRESS

The Opinion on the outline for the new Guidance Document was presented, discussed and adopted. The Opinion provides the roadmap for how the guidance will be developed. The three rapporteurs who were appointed at the January Plenary were confirmed. The adopted Opinion is scheduled for publication by mid April.

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The Chairpersons of the WG gave an update on the development of the new GD on estimating emissions from a wide range of protected crop systems (greenhouses and covered crops). The report on the PPR stakeholder workshop on Emissions from Protected Crops (PROTEA) held from 17 to 19 November 2009 was published in February. The WG will meet again on 20-21 May.

A second data collection on protected crop structures in the EU is ongoing. An open call for estimation/calculation of emissions of PPPs from protected crops has been launched with deadline of submission of offers by mid-April.

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

The Chairperson of the WG updated the panel on the progress of the work. Two outsourced projects are ongoing on validation of the tiered approach and data collection for crop interception. The outcome of externalised work will be available during 2010. The WG will meet again on 25-26 March and on 18-19 May.

Mr. EGSMOSE presented an outline for a new accelerated procedure for developing the Guidance Document in parallel with the Opinion. The proposed procedure will be applied to the Guidance Document on how to use field persistence and soil accumulation studies for exposure assessment. This advanced draft of the Guidance Document is scheduled for a public web consultation in mid 2010. The second Guidance Document on how to estimate exposure concentrations in soil for arable land will follow later in 2010 applying the same accelerated procedure. The Panel agreed that the proposed procedure would be more efficient and will provide guidance in a shorter time.

4. DRAFT OPINION ON SPECIFIC PROTECTION GOALS: UPDATE ON STAKEHOLDER AND RM CONSULTATION

Ms. NIENSTEDT and Ms. BOPP informed the participants about the status of the stakeholder workshop and risk manager consultation.

The stakeholder workshop "*Protection Goals for Environmental Risk Assessment of Pesticides - What and where to protect?*" planned for 15-16 April in Parma, has been organised. Confirmations have been received from the 80 participants plus rapporteurs of the workshop. All the material for the workshop will be made available to the participants on 26 March, including the draft Opinion on development of specific protection goals and the presentations.

The risk manager consultation will be organised together with DG SANCO and will be held on 11 and 12 May in Brussels, back to back with the next SCoFCAH. The material for the preparation phase of the consultation, including the draft Opinion on development of specific protection goals, will be made available on 26 March via CIRCA.

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5. INFORMATION ON ECOREGIONS MANDATE

The rapporteur of the WG Ecoregions informed the Panel about the progress of the Working Group. The mandate deadline needs to be extended and this was agreed by the Panel. The WG plans to submit 2 draft Opinions for adoption by the Panel. One is envisaged for May 2010, the second one for June / July 2010. Additionally a technical report is expected to be issued by the EFSA-AMU unit.

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

The rapporteur gave information about the kick-off meeting with the contractor of the outsourced project. The grant agreement was signed in December 2009 and the contractor started the work in January 2010. The final report is expected in December 2010. A question came up in regard to whether or not the contractor for the project Identification of Cumulative Assessment Groups of Pesticides should provide suggestions for index compounds for all the identified cumulative assessment groups. It was agreed that the PPR Unit will explore the possibilities and the necessity of asking the contractor for delivery of the information.

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

The EFSA secretariat informed the PPR Panel that the public consultation was launched on 1 March and the stakeholders will be able to comment up until 10 May. The secretariat also indicated that in order to comply with new internal standard operating procedures, an internal mandate related to the development of the Guidance Document will be requested via the EFSA Mandate Review Committee, in order to cover the 2 planned public consultations.

A request from the PPR Panel for extending the deadline of the mandate up to 31 December 2011 will also be prepared by the secretariat, in order to cover the entire content (single exposure assessment and cumulative exposure assessment) of the Terms of References adopted in 2008.

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

The chair of the WG on the Toxicological relevance of pesticide metabolites for dietary risk assessment presented the Terms of Reference, the reason behind the mandate, the planned timeline and the conclusions of the outsourced projects related to this mandate, namely the TTC concept, impact of metabolism and applicability of QSAR. The Panel was also informed about the progress made by the Working Group since the last Plenary meeting.

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The EFSA secretariat explained that the size of this Working Group is very large due to the broad expertise necessary for this mandate. The best use of resources, as well as the use of telemeetings in small subgroups focusing on specific issues, should be explored and discussed during the next WG meeting in April.

The deadline for adoption of the Opinion is September 2011, as the mandate provided the Panel with a period of 18 months after completion of the last of the 3 outsourced activities.

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

The rapporteur informed the Panel about the outcome of the outsourced project. The final report was accepted in January 2010. It contains the revision of the most recent literature and a proposal for the draft Guidance Document. Using this report as a starting document, the WG on the Toxicology of Pesticides recently started the elaboration of the Opinion on the revision of the Guidance Document on Dermal Absorption. The rapporteur presented the planned structure and content of the Opinion. The proposal for the draft GD will be in an annex to the Opinion. The first draft of the GD was circulated to the WG before the plenary meeting. The first discussion took place on the WG meeting organized after the plenary meeting. The Opinion is expected to be ready for public consultation during the July plenary meeting and it may be ready for adoption in December.

The EFSA secretariat informed the Panel about the teleconference organized by the OECD Expert Group on Dermal Absorption. The rapporteur underpinned that the proposed GD in preparation by the PPR Panel will consider the content of the OECD Guidance Notes on Dermal Absorption and will contain suggestions for “optimisation” of the OECD document to the specificity of pesticide products and formulations.

10. DISCUSSION OF TERMS OF REFERENCES FOR AN OPINION ON THE ACUTE DIETARY INTAKE ASSESSMENT OF PESTICIDE RESIDUES IN FRUIT AND VEGETABLES: IMPACT OF CHANGING VARIABLES IN THE IESTI EQUATIONS ON THE LEVEL OF PROTECTION.

The EFSA secretariat informed the Panel of this possible new mandate which was first discussed during the last meeting of the Pesticide Steering Committee. Some Member States expressed the need for investigation of the impact of simultaneous change of 2 variables of the IESTI equation on the level of consumer protection. The Pesticide Steering Committee agreed that this topic could be prioritised so as not to penalise the current ongoing PPR Panel activities and under restriction that a strong agreement between Commission and Member States could be reached on the exact objectives of this mandate.

A draft terms of reference for this mandate has been sent to the Commission for formal endorsement by the SCFCAH. The secretariat also informed the Panel that EFSA would only act upon a formal request of the Commission considering the current breach of resources of the PPR Unit.

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The Chair of the Panel highlighted the importance of clarity and coherence between Risk Assessment and Risk Management, especially in this case, as a mandate on this topic already resulted in a high investment of resources in 2007.

11. MISCELLANEOUS:

- **Information on AMU WG on submission of scientific peer-reviewed open literature as requested by Regulation 1107/2009**

Mr. O. MAGRANS (PRAPeR unit) and Ms. E. AIASSA (AMU unit) explained the state of the preparation of a Guidance Document on the implementation of Art 8.5 by the WG on the scientific peer-reviewed open literature. A draft will be circulated to PPR Panel members on 21 April, their comments will be collected until 5 May. The WG will finalize the Guidance on 19-20 May.

- **Feedback from the Scientific Committee and its Working Groups**

The Chairman informed the panel about the latest developments at the SC in February in Paris, in particular regarding Endocrine Disruptor issues. He also informed the panel about the work of the various WGs under the SC. Ms. K. HIRSCH-ERNST informed everyone about the Forum on Consumer Protection in Berlin on 19-20 April organised by BfR and AFSSA on Endocrine Disruptors. Mr. H. STEINKELLNER has already been invited to make a presentation.

- **Feedback from the discussion with MS at the Pesticide Steering Committee 17 February on the list of new requests for Guidance Documents to be prepared by the PPR Panel and on the Working Document DG SANCO**

Mr. L. MOHIMONT gave an overview on the discussion of the Table of priorities. For topics considered as relevant, respective requestors have been asked by the Pesticide Steering Committee to draft terms of references. These terms of reference will be rediscussed at the June PSC for the possible route to follow. The Panel will be regularly informed as this will determine a large part of its activities from 2012.

- **EPA request for EFSA/EPA Cooperation on the use of unit-to-unit variability in dietary risk assessment of pesticides residues.**

Mr. L. MOHIMONT explained the change of EPA's Risk Assessment approach regarding unit-to-unit variability in regulatory modelling of consumer exposure in the United States. A request for collaboration on this topic has been addressed to EFSA. The content of the reply is under internal discussion and the PPR Panel will be kept informed.

The next Plenary meeting will take place on **19-20 May 2010** in Parma, starting at **14h00** on 19 May.
