

PANEL ON PLANT PROTECTION PRODUCTS AND THEIR RESIDUES

**54TH PLENARY MEETING OF THE SCIENTIFIC PANEL ON
PLANT PROTECTION PRODUCTS AND THEIR RESIDUES**

HELD IN PARMA ON 23-24 NOVEMBER 2011

(ADOPTED BY WRITTEN PROCEDURE ON 5 JANUARY 2012)

#	Items
1.	Opening, apologies for absence
2.	Adoption of the draft agenda
3.	Declarations of interest
4.	Guidance on the use of probabilistic methodologies for modelling dietary exposure to pesticide residues.
5.	Opinion on the evaluation of the toxicological relevance of metabolites and degradates of pesticide active substances for the dietary risk assessment.
6.	Opinion on the clustering and ranking of emissions from protected crops.
7.	Guidance on terrestrial ecotoxicology.
8.	Opinion on the science behind the development of a risk assessment of PPPs on bees (<i>Apis mellifera</i> and <i>Bombus spp.</i>)
9.	Guidance on aquatic ecotoxicology.
10.	Draft mandate on an opinion on overarching principles in environmental risk assessment.
11.	Opinion on the science behind the guidance for scenario selection and scenario parameterisation for predicting PEC in soil.
12.	Opinion on the identification of pesticides to be included in cumulative assessment groups on the basis of their toxicological profile.
13.	Opinions on the 2009 report of the FOCUS Groundwater WG.
14.	Miscellaneous: <ul style="list-style-type: none">- Feed-back from the Scientific Committee and its WGs, including the opinion on statistical significance and biological relevance- Presentation of the new Audio/Web conferencing tool- Information Exchange Platform

PANEL ON PLANT PROTECTION PRODUCTS AND THEIR RESIDUES

PARTICIPANTS

Members of the PPR Panel

Mr J. BOESTEN, Mr T. BROCK, Mr E. CAPRI, Mr A. HARDY (Chair), Ms K. HIRSCH-ERNST, Ms S. HOUGAARD BENNEKOU, Mr M. KLEIN, Mr R. LUTTIK, Ms K. MACHERA, Ms B. OSSENDORP, Ms A. PETERSEN, Ms Y. PICO, Mr A. SCHAEFFER, Mr W. STEURBAUT, Ms A. STROMBERG, Ms M. TASHEVA, Mr T. VAN DER LINDEN, Ms C. VLEMINCKX

Apologies

Ms C. BOLOGNESI, Mr A. HART, Mr P. SOUSA

Commission

Ms J. HOUINS-ROULET (DG SANCO)

EFSA

Mr S. BRONZWAER, Mr M. RAGNOLI, Mr G. ZANCANARO

PPR Panel secretariat: Mr L. MOHIMONT, Ms M. ARENA, Ms S. BOPP, Mr M. EGSMOSE, Mr I. SEBESTYEN, Mr H. STEINKELLNER, Mr F. STREISSEL, Ms G. BOSCHETTO, Ms A. PASQUIN, Ms M. SODANI, Ms J. RICKETTS

1. OPENING, APOLOGIES FOR ABSENCE

Apologies were received from Ms BOLOGNESI, Mr HART and Mr SOUSA.

2. ADOPTION OF THE DRAFT AGENDA

The agenda was adopted.

3. DECLARATIONS OF INTEREST

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. GUIDANCE ON THE USE OF PROBABILISTIC METHODOLOGY FOR MODELLING DIETARY EXPOSURE TO PESTICIDE RESIDUES

The secretariat informed the Panel that editorial work is still ongoing before the second public consultation on the draft guidance. It was pointed out that clear and helpful answers were received from the Commission in response to EFSA's questions on cumulative risk and exposure assessment. These answers, together with the comments received in the second public consultation, will be taken into account for finalising the guidance. Since finalisation of the guidance was not

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feasible within the foreseen deadline (end of 2011) the Pesticide Unit will request a further extension of the deadline.

5. OPINION ON THE EVALUATION OF THE TOXICOLOGICAL RELEVANCE OF METABOLITES AND DEGRADATES OF PESTICIDE ACTIVE SUBSTANCES FOR THE DIETARY RISK ASSESSMENT

The Chair of the WG drafting this opinion gave an overview on the current status of the draft opinion that has been distributed to the Panel for commenting. Written comments have been received that were to be discussed at the PPR WG meeting taking place after the meeting. The Chair pointed out that in particular the chapters dealing with application of the TTC concept and computational models for assessment of pesticide metabolites would benefit from a thorough peer-review by experts that had not been deeply involved in the work throughout the process, to make sure that the rationale is easy to follow.

It was agreed that two Panel members would give this additional support to the WG in reviewing and commenting on the relevant chapters of the opinion.

6. OPINION ON THE CLUSTERING AND RANKING OF EMISSIONS FROM PROTECTED CROPS

The Rapporteur gave an update on the development of the opinion. The WG will meet again on 24-25 November and will consider the remarks received from the stakeholder consultation on the draft opinion. An EFSA technical report on responses to the stakeholder comments is under preparation. The draft opinion is foreseen for adoption before May 2012.

An EFSA guidance document based on the adopted opinion will be prepared by an EFSA WG.

7. GUIDANCE ON TERRESTRIAL ECOTOXICOLOGY

An update on the work of the different WGs was given by the secretariat. The in-soil risk assessment WG is planned to have its first meeting in November 2012. The WG on non-target plants will have its next meetings in March and July 2012. The WG on non-target arthropods is still being established. Experts were identified in the EFSA expert data base matching the expertise identified in the Panel meeting in September. It is envisaged to have a first meeting in April in order to start working on validation of trigger values. Information from the non-target arthropod risk assessment may be used in the risk assessment for bees. Validation of trigger values used in the non-target arthropod risk assessment will be a useful input for the mandate on the bee risk assessment.

8. OPINION ON THE SCIENCE BEHIND THE DEVELOPMENT OF A RISK ASSESSMENT OF PPPs IN BEES (*Apis mellifera* and *Bombus spp.*)

The secretariat presented the progress made in the WG on bee risk assessment. First proposals on specific protection goals were presented. Information on exposure routes was compiled. Existing risk assessment schemes were analysed to see whether they cover all effects considered of importance for different life stages of bees. Cumulative and synergistic effects will be a separate

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chapter in the opinion. The Chair of the WG presented a first draft of the chapter to the Panel. It is recommended to use dose addition as a default in the risk assessment together with an appropriate safety factor. Synergism was demonstrated for only a few compounds. It was proposed to send the draft chapter to the toxicologists of the Panel for comments. The Panel members offered their help to support the work in the chapter on synergism.

9. GUIDANCE ON AQUATIC ECOTOXICOLOGY

The Chair of the WG gave a presentation to update the Panel on the progress in the WG Aquatic Ecotoxicology. The WG is currently working on drafting the “Guidance Document on tiered risk assessment for aquatic organisms in edge-of-field surface waters” (module 1 of the four GDs covered in the mandate). The WG is progressing on the guidance on higher tier studies but with delays compared to the original planning due to the time taken for its establishment. In addition, Member States, after consultation on the work plan via the Standing Committee in May 2011, recommended considering the new data requirements related to Regulation 1107/2009, which are not yet available. Therefore, it was proposed to request an extension of the mandate by 1 year. Asking for an extension of module 1, however, implies that all 4 guidance documents to be developed will be delayed by one year. The Chair of the PPR Panel will formally request the extension to the Executive Director.

The Panel further considers that the new guidance documents also need to cover guidance on exposure assessment. In the EFSA PPR opinion on defining specific protection goals (EFSA 2010), the PPR Panel emphasised the need for spatio-temporal definition of the exposure and effect assessment goals. Regarding aquatic ecotoxicology, the Panel agreed to propose a “Scientific Opinion on the evaluation of the level of protection of the FOCUS Step-3 surface water scenarios” which will partly support module 1 (as mentioned above) and mainly module 2 (Guidance Document on ERA modelling approaches for aquatic organisms) under the mandate of the GD on Aquatic Ecotoxicology. The Commission will be invited to make suggestions with regards to this new mandate. The Chair of the PPR Panel will formally propose the new question to the Executive Director.

10. DRAFT MANDATE ON AN OPINION ON OVERARCHING PRINCIPLES IN ENVIRONMENTAL RISK ASSESSMENT

Important overarching issues have been identified in the revision process of the guidance documents on Terrestrial and Aquatic Ecotoxicology.

In the Public Consultation held in 2008, many stakeholders also expressed a strong need to have a more harmonised approach in the different fields of ecotoxicological RA, in order to be more consistent in the RA schemes for the aquatic and terrestrial fields.

Handling these issues centrally will ensure this harmonisation.

Therefore, it is appropriate to give more detailed information on these identified overarching issues in a separate opinion to which the individual sectorial GDs will refer. This will also keep the GDs more concise and easier to understand and apply.

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The Panel agreed therefore on a proposal for a “Scientific Opinion on Overarching Principles for the revision of the Guidance Documents on Aquatic and Terrestrial Ecotoxicology (SANCO/3268/2001 rev.4 (final), 17 October 2002 and SANCO/10329/2002 rev 2 final, 17 October 2002, respectively EFSA Mandates 2009-0001 and 2009-0002)”. The principles might also have wider consequences for the revision of other Ecotoxicological GDs (e.g. GD on birds and mammals).

The Commission will be invited to make suggestions with regards to this new mandate. The Chair of the PPR Panel will formally propose the new question to the Executive Director.

11. OPINION ON THE SCIENCE BEHIND THE GUIDANCE FOR SCENARIO SELECTION AND SCENARIO PARAMETERISATION FOR PREDICTING PEC IN SOIL

The Rapporteur gave an update on the development of the draft opinion. The WG met on 21-23 November and considered the remarks received from the stakeholder consultation on the draft opinion. An EFSA technical report on responses to the stakeholder comments is under preparation. The draft opinion is foreseen for adoption in January 2012.

An EFSA guidance document, based on the adopted opinion, will be prepared by an EFSA WG.

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

The Chair of the PPR WG on Cumulative Assessment Groups, gave a presentation on the background and the ongoing work of the WG on cumulative risk assessment. She expressed strong concerns about the still remaining workload. The answers to the specific questions on cumulative risk assessment received from the Commission were, however, helpful for continuing the work. EFSA informed the PPR Panel that the Technical University of Denmark submitted the final scientific report on the identification of cumulative assessment groups of pesticides.

The PPR Panel encouraged EFSA to consider organising a public consultation on the draft opinion in order to gain the view of concerned stakeholders.

13. OPINIONS ON THE 2009 REPORT OF THE FOCUS GROUNDWATER WG

The secretariat informed the Panel about the request from the Commission for two separate opinions on the FOCUS groundwater report for assessing potential movement of active substances and their metabolites to groundwater in EU (2009).

The amended mandate was received and has been accepted by the EFSA Mandate Review Committee. Further to an exchange between EFSA and the Commission service the dates for adoption have been agreed and fixed: 28 February 2013 for the first opinion and by 30 June 2013 for the second opinion.

The Chair of the Panel and the members agreed to the composition of the WG proposed during the meeting. The proposed external experts will provide the following expertise to the WG:

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- modeling and monitoring in catchment scale
- hydrology and multivariate statistics
- functional pesticide fate models
- scenario selection
- sorption and degradation

Another two external hearing experts, with particularly relevant knowledge for the mandate, were proposed by the Panel to participate in WG meetings. The request will be forwarded to the competent director of EFSA.

14. MISCELLANEOUS

- **Feed-back from the Scientific Committee and its WGs, including the opinion on statistical significance and biological relevance**

The Chair of the Panel gave an overview of the points discussed at the last meeting of the Scientific Committee in November. In particular, an overview of EFSA's work in relation to the risk assessment of pesticides has been given by the Pesticides Unit, with particular emphasis on the mandates concerning cumulative risk assessment.

EFSA gave a presentation of the opinion of the Scientific Committee on statistical significance and biological relevance. This opinion has been adopted by the Scientific Committee and Scientific Panels of EFSA in view of a consistent use of these concepts.

- **Presentation of the new Audio/Web conferencing tool**

EFSA gave a presentation of the new web conferencing tool (Lync 2010) and its functionalities. The tool has already been successfully implemented in Panel and WG meetings.

- **Information Exchange Platform**

EFSA gave a presentation on the essential features of the Information Exchange Platform which is managed by EFSA in cooperation with Member States. This platform facilitates the exchange of risk assessment outputs undertaken by official bodies in Member States.

The next Plenary meeting will take place on 25-26 January 2012 in Parma, starting at **14h00** on 25 January.
