PANEL ON PLANT PROTECTION PRODUCTS AND THEIR RESIDUES

57TH PLENARY MEETING OF THE SCIENTIFIC PANEL ON PLANT PROTECTION PRODUCTS AND THEIR RESIDUES

PUBLICLY OPENED SESSION

HELD IN PARMA ON 18-19 APRIL 2012

(ADOPTED BY WRITTEN PROCEDURE ON 24 MAY 2012)

#	Items
1.	Opening, apologies for absence
2.	Adoption of the draft agenda
3.	Declarations of interest
4.	Pilot project on the attendance of observers to the meeting of the PPR Panel
5.	Opinion on the identification of pesticides to be included in cumulative assessment groups on the basis of their toxicological profile
6.	Guidance on dermal absorption
7.	Opinion on the science behind the development of a risk assessment of plant protection products on bees (*Apis mellifera* and *Bombus spp.*)
8.	Opinion on the evaluation of the toxicological relevance of metabolites and degradates of pesticide active substances for the dietary risk assessment
9.	Guidance on the use of probabilistic methodologies for modelling dietary exposure to pesticide residues
10.	Guidance on aquatic ecotoxicology
11.	Miscellaneous
12.	Questions and Answers

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PARTICIPANTS

Members of the PPR Panel

Mr J. BOESTEN, Ms C. BOLOGNESI, Mr T. BROCK, Mr E. CAPRI, Mr A. HARDY (Chair), Mr A. HART, 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

EU Commission

Ms J. HOUINS-ROULET (DG SANCO)

Observers

Mr J.C. BOISSINOT (STAPHYT), Ms M. BROSS (BASF), Mr W. DE MEY (Japan Agro Services), Mr A. NIKOLAKIS (Bayer CropScience AG), Mr P. PARSONS (Syngenta), Mr P. SWEENEY (Syngenta)

EFSA

Ms M. LAHANIATIS, Mr D. DETKEN

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

Apologies

Ms K. HIRSCH-ERNST, Mr P.SOUSA

1. OPENING, APOLOGIES FOR ABSENCE

The Chair opened the meeting and welcomed the Panel members and the observers. Apologies were received from Ms K. HIRSCH-ERNST and Mr P.SOUSA.

2. ADOPTION OF THE DRAFT AGENDA

The agenda was adopted, with the addition of a presentation of the pilot project on the attendance of observers to the meeting.

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. PILOT PROJECT ON THE ATTENDANCE OF OBSERVERS TO THE MEETING OF THE PPR PANEL

The Chair welcomed the Observers who were attending this Plenary meeting as part of a pilot project underpinning EFSA's commitment to openness and transparency. The aim of this pilot phase is to test the feasibility of opening up the risk assessment process to Observers from interested parties, providing them with the opportunity to raise questions in relation to EFSA's work. Observers were invited to introduce themselves before being presented the code of conduct to be followed during and after attendance.

Observers and members of the PPR Panel were invited to fill in a feedback form at the end of the meeting. Comments and suggestions will be used to improve future open Plenary meetings organised by EFSA.

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

The Chair of the WG informed the PPR Panel about the progress on the opinion. She made the Panel aware of concerns of WG members in regard to their workload. The PPR Panel reiterated that the tasks entrusted to the WG are restricted to the content of the Terms of Reference as sent by EFSA. The secretariat informed the Panel that further preparatory work on this opinion is currently being outsourced by EFSA in the form of an open call for procurement. The legal and technical timelines incurred with this new call made an extension of the timeline of the mandate inevitable. The Chair noted that the public consultation on the draft opinion, recommended to EFSA by the PPR Panel, needs to be considered when extending the timeline for adoption of the opinion.

6. GUIDANCE ON DERMAL ABSORPTION

The Rapporteur gave an overview about all the past activities and initiatives of the PPR Panel and the Pesticide Unit within the frame of the mandate that resulted in the current draft guidance, tabled for adoption during the Plenary meeting. Several comments regarding risk management elements in the draft guidance were received from the Commission in response to a letter sent by EFSA and these have now been introduced in the draft guidance. The respective changes made to the draft opinion by the WG were presented and explained by the Rapporteur and endorsed by the Panel.

After making further amendments based on comments from Panel members aimed at improving the clarity of the document, the guidance was adopted by the PPR Panel.

7. OPINION ON THE SCIENCE BEHIND THE DEVELOPMENT OF A RISK ASSESSMENT OF PLANT PROTECTION PRODUCTS ON BEES (*Apis mellifera* and *Bombus spp.*)

An overview was given on the comments received from Panel members on the draft opinion and on how the working group addressed the comments. The updated opinion was presented and discussed. The opinion was adopted after some discussion and inclusion of some amendments.

8. 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 gave an overview about the activities of the WG and the Pesticides Unit in preparation of the draft opinion and presented an update on the progress in the drafting of the document. Particular emphasis was given to the chapters on the assessment of isomers. She noted that the comments received from Panel members have been included in the last version of the draft opinion. Two Panel members offered to review the scientific wording of the draft opinion before its foreseen adoption at the Plenary meeting in June.

Mr. D. DETKEN informed the Panel on EFSA's policy on the handling of requests of access to EFSA's documents in application of Regulation (EC) No 1049/2001 on public access to documents.

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

The Chair of the WG informed the PPR Panel about the changes in the draft guidance resulting from the comments received during the second public consultation. Two WG meetings will take place before the next Plenary meeting where the adoption of the guidance is foreseen.

10. GUIDANCE ON AQUATIC ECOTOXICOLOGY

An update on the status and progress of the development of the guidance document on tiered risk assessment for aquatic organisms in edge-of-field surface water was presented. The WG Aquatic Ecotoxicolgy held 3 webconferences in March and made progress on several chapters. However, there are still open issues in most of the chapters. Therefore it was agreed to postpone the presentation of the first complete draft of the GD to the Panel meeting in June 2012.

The Panel was informed that due to changes in the intended scope of the guidance document regarding the exposure assessment, a re-evaluation of the interests of the Chair and members of the WG led to the conclusion that Mr KLEIN could no longer chair the WG. The WG is therefore without a Chair. The Panel secretariat will take over this role until the Panel renewal in July 2012 when the situation will be re-evaluated.

11. MISCELLANEOUS

The Secretariat informed the Panel that the stakeholder report on the draft opinion on clustering and ranking of emissions of plant protection products from protected crops (greenhouses and crops grown under cover) to relevant environmental compartments, has now been published.

12. QUESTIONS AND ANSWERS

The Chair granted the Observers the opportunity to ask questions in a dedicated session, after they had observed the meeting. These questions, which had been circulated at least one week in advance of the meeting, were answered by the PPR Panel.

Question from Mr. Jean-Christophe BOISSINOT: *Regarding the opinion on clustering and ranking of PPP from protected crops to environmental compartments (document adopted 8 March): in the recommendations section, it is foreseen as useful to establish a list of protected crops and link these to exposure assessment scenarios. When is this list likely to be available for review*?

It is envisaged that part of the opinion is translated into an EFSA guidance document for use in daily risk assessment by applicants and risk assessors in authorities. Other parts of the adopted opinion need further work to establish risk assessment methodology. The list of protected crops similar to the Dutch and UK list in the opinion in exposure in soil (EFSA Journal 2012;10(2):2562) could partially be established as part of the guidance document. Given current knowledge on emissions from protected crops and greenhouses, the linking to scenarios can only be done after the scenarios have been established. No date can be given for this list for the moment as it is up to the Pesticide Review Committee to prioritise this guidance when a proposal from Member States has been received.

Question from Ms. Monica BROSS: *My main interest would be to learn more about the status, timelines and further proceedings (e.g. inclusion of case studies) of the probabilistic guidance document on dietary exposure assessment.*

The adoption of the guidance document on the use of probabilistic methodology is an essential step before practical implementation of cumulative risk assessment in routine MRL setting. Future activities in this respect will include:

- Development or adaptation of software to make the proposed approaches for basic probabilistic assessments available to users in a friendly and practical form, with appropriate user guidance.
- Organisation in quality-assured and accessible form of the data needed for probabilistic assessments, including consumption data, residues from monitoring and field trials, processing factors, food conversion factors and the registration status of substances and uses.
- Additional case studies to demonstrate and evaluate the approaches recommended in this document.
- Develop more specific guidance and methods for refined assessment, including:
  - Improved approaches for modelling variation of residues between lots or samples, especially in the upper tails.
  - Options for taking account of uncertainty arising from parameters for which only very few data are available.
  - Further improvement and evaluation of methods for modelling habitual consumption or exposure for chronic exposure assessments, including methods suitable for assessments involving multiple food types.
  - Modelling of repeated acute exposures and/or exposures over time periods intermediate between acute and chronic, if required by risk managers.
- Consultation with risk managers to explore thresholds for use in decision-making, and to consider how these thresholds should take account of factors such as the severity of effects and the level of uncertainty.

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Question from Mr. Alexander NIKOLAKIS: *How does the panel consider expert judgement in higher tier studies, regarding the separation between treatment-related and non-treatment related effects?*

The distinction between treatment and non-treatment related effects in higher tier studies depends mainly on the experimental design, e.g. the inclusion of sufficient replicates for the control and treated test systems. The response in the treated test systems is compared with the response of the same endpoint in the control test systems by using statistics and ecotoxicological/ecological knowledge. Since higher-tier studies are usually complex, the evaluation of higher tier studies will always be based on expert judgement and on the clarity of the specific protection goals defined (in terms of practicality and feasibility). In this context it is very helpful if besides guidance on the design of higher-tier studies also guidance is developed on how to evaluate and interpret higher-tier studies. This is for example done for aquatic micro-/mesocosm studies (e.g. De Jong et al. 2008: Guidance for summarizing and evaluating aquatic micro- and mesocosm studies) and will be addressed in the revised Guidance on Risk Assessment for Aquatic Organisms of the PPR Panel. Similar guidance on higher tier study design and evaluation should also be developed for higher tier studies with terrestrial organisms.

The next Plenary meeting will take place on 20-21 June 2012 in Parma, starting at 14h00 on 20 June.